Summary of Changes
BMT CTN 1302 Allo Myeloma Amendment Version 3.0
Dated: December 19, 2017

This document includes a detailed summary of changes to the BMT CTN 1302 protocol since version 2.0. The following major changes have been incorporated into version 3.0 of the protocol, dated December 19, 2017:

1. The following major changes were made to the eligibility criteria:
    a. Maximum eligible age was expanded to 70.0 years (#1, #3, #9, #13, and #29)
    b. Time to progression was extended to 24.0 months (#2, #4-6, #9, #14, and #30)
    c. Added guidance for disease response for patients with low burden of disease (#8, #14, and #25)
2. The following major updates were made to the study drug risk language per the current Investigators Brochures for Ixazomib (Ed11) and Bortezomib (Ed19)
    a. TEN, DRESS syndrome, and pemphigus vulgaris were specified as rare risks under rash for ixazomib (#16)
    b. PML was detailed as a rare risk of ixazomib (#21)
    c. Alopecia and peripheral edema were added as risks of bortezomib (#23, #31, and #34)
    d. Fever, dyspnea, dysgeusia, headache, cough, dizziness, and insomnia were removed from ixazomib risks (#32)
3. Updates were made throughout the document to correct typos and formatting, and to improve clarity

The following changes, and the rationale for the changes, were made to the attached protocol in this amendment:

#	Section number, title, and page number of original	Original text:	Changed to:	Rationale
1.	Protocol Synopsis, Eligibility Criteria	Patients aged ≥ 18.0 years and < 66.0 years of age at the time of enrollment	Patients aged ≥ 18.0 years and ≤ 70.0 years at the time of enrollment	Expanded maximum eligible age to 70.0 years
2.	Protocol Synopsis, Eligibility Criteria	1) high risk multiple myeloma in partial response (PR) or better disease response with no prior progression *and* within 18 months from initiation	1) high risk multiple myeloma in partial response (PR) or better with no prior progression *and* are ≤ 24.0 months after autologous HCT (single or planned	Increased time to progression to 24.0 months; separated time

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		of systemic anti-myeloma therapy which may include single or planned tandem autologous transplant, *or* 2) high risk multiple myeloma in very good partial response (VGPR) or better with 1 prior progression ≤18.0 months from initiating anti-myeloma therapy which may include single or planned tandem autologous HCT; *or* 3) standard risk multiple myeloma in VGPR or better with 1 prior disease progression ≤18.0 months from an autologous HCT (single or tandem) 4) plasma cell leukemia in VGPR or better with no prior progression *and* ≤18.0 months from initiation of systemic anti-myeloma therapy which may include single autologous transplant	tandem), or are ≤ 24.0 months after initiation of systemic anti-myeloma therapy with no autologous HCT; *or* 2) high risk multiple myeloma in very good partial response (VGPR) or better with 1 prior progression which occurred ≤ 24.0 months after autologous HCT (single or planned tandem), or ≤ 24.0 months after initiation of systemic anti-myeloma therapy with no autologous HCT; *or* 3) standard risk multiple myeloma in VGPR or better with 1 prior progression ≤ 24.0 months from autologous HCT (single or planned tandem) 4) plasma cell leukemia in VGPR or better with no prior progression *and* are ≤ 18.0 months after autologous HCT, or are ≤ 18.0 months after initiation of systemic anti-myeloma therapy with no autologous HCT	from prior transplant vs. time from initiation of anti-myeloma therapy without transplant, for clarity
3.	Study Schema, Inclusion Criteria	1. Age ≥18.0 and <66.0-years at the time of enrollment	1. Age ≥ 18.0 and ≤ 70.0 years at the time of enrollment	Expanded maximum eligible age to 70.0 years
4.	Study Schema, Table 1: Disease Criteria for Eligible Patients	≤18.0 months from initiation of systemic anti-myeloma therapy which	≤ 24.0 months from autologous HCT (single or planned tandem), or from initiation of	Increased time to progression to 24.0 months;

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		may include single or planned tandem autologous transplant	systemic anti-myeloma therapy with no autologous HCT	separated time from prior transplant vs. time from initiation of anti-myeloma therapy without transplant, for clarity
5.	Study Schema, Table 1: Disease Criteria for Eligible Patients	progression or relapse ≤ 18.0 months from initiation of systemic anti-myeloma therapy which may include single or planned tandem autologous transplant	progression or relapse ≤ 24.0 months from autologous HCT (single or planned tandem), or from initiation of systemic anti-myeloma therapy with no autologous HCT	Increased time to progression to 24.0 months; separated time from prior transplant vs. time from initiation of anti-myeloma therapy without transplant, for clarity
6.	Study Schema, Table 1: Disease Criteria for Eligible Patients	progression or relapse ≤ 18.0 months from an autologous HCT which may include single or planned tandem	progression or relapse ≤ 24.0 months from single or planned tandem autologous HCT	Increased time to progression to 24.0 months
7.	Study Schema, Table 1: Disease Criteria for Eligible Patients	≤ 18.0 months from initiation of systemic anti-myeloma therapy which may include single or planned tandem autologous transplant	≤ 18.0 months after autologous HCT, or after initiation of systemic anti-myeloma therapy	Separated time from prior transplant vs. time from initiation of anti-myeloma therapy without

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				transplant, for clarity
8.	Study Schema, Table 1: Disease Criteria for Eligible Patients	*N/A; footnote added*	[2]Patients with one prior progression without measurable monoclonal paraprotein at the time of disease progression or relapse (< 1.0 g/dl in serum or < 200 mg/24hrs in urine) may be considered to have met VGPR criteria if < 5% plasma cells in bone marrow *and* ≥ 90% decline in the difference between involved and uninvolved FLC levels from baseline (time of progression/relapse). In patients with IgG kappa multiple myeloma receiving daratumumab: International Myeloma Working Group (IMWG) criteria for VGPR may not be achieved since daratumumab is known to increase the IgG kappa spike. In such cases the FLC and marrow may be used to establish VGPR, as above, with prior approval from the protocol co-chairs.	Added disease response guidance for patients with low burden of disease and patients receiving daratumumab
9.	Outline of Treatment Plan	≥18.0 years to <66.0 years High Risk Multiple Myeloma ≤ 18.0 months from anti-myeloma therapy without progression *OR* High Risk Multiple Myeloma with progression ≤ 18.0 months from anti-myeloma therapy *OR*	≥ 18.0 years to ≤ 70.0 years High Risk Multiple Myeloma ≤ 24.0 months from anti-myeloma therapy without progression *OR* High Risk Multiple Myeloma with progression ≤ 24.0 months from anti-myeloma therapy *OR* Standard Risk Progression ≤ 24.0 months	Expanded maximum eligible age to 70.0; increased time to progression to 24.0 months

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		Standard Risk Progression ≤18.0 months from prior autoHCT *OR* Plasma Cell Leukemia	from prior autoHCT *OR* Plasma Cell Leukemia ≤ 18.0 months from anti-myeloma therapy	
10.	Section 1.8.1. Preclinical Experience	Please refer to the current MLN9708 Investigator's Brochure (IB) and Safety Management Attachment (SMA).	Please refer to the current MLN9708 Investigator's Brochure (IB).	Per pharmaceutical contributor, SMA is now incorporated within the IB
11.	Section 1.8.3. Pharmacokinetics and Drug Metabolism	Please refer to the current IB and Safety Management Attachment (SMA) for information on the PK for IV doses of MLN9708	Please refer to the current IB for information on the PK for IV doses of MLN9708.	Per pharmaceutical contributor, SMA is now incorporated within the IB
12.	Section 1.8.6. Relapsed and/or Refractory Multiple Myeloma	The potential risks reported with MLN9708 use, pooled from all studies using the oral formulations, were anticipated based on preclinical data and previous experience with VELCADE and are noted in the MLN9708 IB, SMA, and ICF documents. Please refer to the MLN9708 IB and SMA for further information.	The potential risks reported with MLN9708 use, pooled from all studies using the oral formulations, were anticipated based on preclinical data and previous experience with VELCADE and are noted in the MLN9708 IB and ICF documents. Please refer to the MLN9708 IB for further information.	Per pharmaceutical contributor, SMA is now incorporated within the IB
13.	Section 2.3.1. Inclusion Criteria	1. Age ≥ 18.0 years and < 60.0 years at the time of enrollment.	1. Age ≥ 18.0 years and ≤ 70.0 years at the time of enrollment.	Expanded maximum eligible age to 70.0 years

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14.	Section 2.3.1. Inclusion Criteria	a. Patients with high risk multiple myeloma in partial response (PR) or better at the time of enrollment with no prior progression *and* ≤18.0 months from initiation of systemic anti-myeloma therapy, which may include single or planned tandem autologous HCT. b. Patients with high risk multiple myeloma (criterion 3a above) in very good partial response (VGPR) or better at the time of enrollment with 1 prior progression ≤18.0 months from initiation of systemic anti-myeloma, which may include single or planned tandem autologous HCT *or* c. Patients with standard risk multiple myeloma in VGPR or better at the time of enrollment with 1 prior progression ≤18.0 months from a single or planned tandem autologous HCT *or* d. Patients with primary plasma cell leukemia in VGPR or better at the time of enrollment with no prior disease progression *and* ≤18.0 months prior to initiation of anti-myeloma therapy which may include	a. Patients with high risk multiple myeloma in partial response (PR) or better with no prior progression *and* are ≤ 24.0 months after autologous HCT (single or planned tandem), or are ≤ 24.0 months after initiation of systemic anti-myeloma therapy for patients without prior autologous HCT; *or* b. Patients with high risk multiple myeloma (see criterion 2.a.i. above) in very good partial response (VGPR) or better with 1 prior progression which occurred ≤ 24.0 months from autologous HCT (single or planned tandem), or ≤ 24.0 months from initiation of systemic anti-myeloma therapy for patients without prior autologous HCT; *or* i. Patients with one prior progression without measurable monoclonal paraprotein at the time of disease progression or relapse (< 1.0 g/dl in serum or < 200 mg/24hrs in urine) may be considered to have met VGPR criteria if < 5% plasma cells in bone marrow *and* ≥ 90% decline in the difference between involved and uninvolved FLC levels from baseline (time of progression/relapse).	Increased time to progression to 24.0 months; separated time from prior transplant vs. time from initiation of anti-myeloma therapy without transplant, for clarity; added disease response guidance for patients with low burden of disease and patients receiving daratumumab

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		single or planned tandem autologous transplant.	ii. In patients with IgG kappa MM receiving daratumumab: International Myeloma Working Group (IMWG) criteria for VGPR may not be achieved since daratumumab is known to increase the IgG kappa spike. In such cases the FLC and marrow may be used to establish VGPR, as above, with prior approval from the protocol co-chairs. c. Patients with standard risk multiple myeloma in VGPR or better (see criteria 2.b.i. and 2.b.ii. above) at the time of enrollment with 1 prior progression ≤ 24.0 months from single or planned tandem autologous HCT; *or* d. Patients with primary plasma cell leukemia in VGPR or better with no prior disease progression *and* are ≤ 18.0 months after autologous HCT, or are ≤ 18.0 months after initiation of anti-myeloma therapy without prior autologous HCT.	
15.	Section 2.5. Supportive Care	• Antimicrobials: Antibacterial, antiviral and antifungal prophylaxis during and after allogeneic HCT are recommended and will be administered based on local institutional guidelines.	• Antimicrobials: Antibacterial, antiviral and antifungal prophylaxis during and after allogeneic HCT are recommended and will be administered based on local institutional guidelines. Consideration of prophylaxis for herpes zoster virus is	Added consideration for prophylaxis for herpes zoster virus per current IB

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			recommended during maintenance therapy.	
16.	Section 2.5.5.3. Erythematous Rash With or Without Pruritus	To date, when it does occur, rash is most commonly reported within the first 3 cycles of therapy. The rash is often transient, self-limiting and is typically Grade 1 to 2 in severity. A rare risk is Stevens-Johnson Syndrome, a severe and potentially life-threatening rash with skin peeling and mouth sores, which should be managed symptomatically according to standard medical practice. Punch biopsies for histopathological analysis are encouraged at the discretion of the investigator.	To date, when it does occur, rash is most commonly reported within the first 3 cycles of therapy. The first incidence of rash events occurred early during treatment, and there was no evidence of increased frequency of rash with prolonged exposure. The rash is often transient, self-limiting (resolves without medical intervention), and is typically Grade 1 to 2 in severity. The rare risks of Stevens-Johnson Syndrome, toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome, and pemphigus vulgaris have been reported in studies when ixazomib (or placebo) has been given in a multi-therapy regimen with concomitant medications known to cause rash and/or in the setting of confounding Treatment Emergent Adverse Events (TEAEs). These severe and potentially life-threatening or deadly conditions may involve rash with skin peeling and mouth sores, which should be managed symptomatically according to standard medical practice. Punch biopsies for histopathological analysis are encouraged at the discretion of the investigator. Study medications should be	Added information about rash risk per current IB

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			discontinued in the event of severe, potentially life-threatening rash.	
17.	Section 2.5.5.4. Thrombocytopenia	Thrombocytopenia may be severe but has been manageable with platelet transfusions according to standard clinical practice.	Thrombocytopenia may be severe but has been manageable with clinical monitoring and platelet transfusions according to standard clinical practice.	Added clinical monitoring management per current IB
18.	Section 2.5.5.7. Hypotension	Blood pressure should be closely monitored while the patient is on study treatment and fluid deficit should be corrected as needed, especially in the setting of concomitant symptoms such as nausea, vomiting, diarrhea, or anorexia.	Blood pressure should be closely monitored while the patient is on study treatment and fluid deficit should be corrected as needed, especially in the setting of concomitant symptoms such as nausea, vomiting, diarrhea, or decreased appetite.	Changed anorexia to decreased appetite per current IB
19.	Section 2.5.5.8. Posterior Reversible Encephalopathy Syndrome	One case of posterior reversible encephalopathy syndrome, which ultimately resolved, has been reported with ixazomib.	Posterior reversible encephalopathy syndrome, which ultimately resolved, has been reported with ixazomib.	Updated per current IB
20.	Section 2.5.5.9. Transverse Myelitis	Transverse myelitis has also been reported with ixazomib. It is not known if ixazomib causes transverse myelitis; however, because it happened to a patient receiving ixazomib, the possibility that ixazomib may have contributed to transverse myelitis cannot be excluded.	Transverse myelitis has also been reported with ixazomib. It is not known if ixazomib causes transverse myelitis; however, the possibility that ixazomib may have contributed to transverse myelitis cannot be excluded. Transverse myelitis should be managed according to standard medical practice.	Updated per current IB

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21.	Section 2.5.6. Progressive Multifocal Leukoencephalopathy (PML) *(new section)*	*N/A, section added*	2.5.6. Progressive Multifocal Leukoencephalopathy (PML) PML, which may be fatal, has occurred in less than 1% of oncology patients receiving ixazomib in combination with other cancer therapies. It is not known whether ixazomib causes PML; however, the possibility that ixazomib may have contributed to PML cannot be excluded. In the event of occurrence of PML, ixazomib should be discontinued and supportive care provided as needed.	Added PML risk language per current IB
22.	Section 2.5.7. Infection	Prophylaxis for infection and surveillance for infection, such as CMV reactivation, is per institutional guidelines.	Prophylaxis for infection and surveillance for infection, such as CMV reactivation, is per institutional guidelines. Investigators should consider the use of antiviral prophylaxis for herpes zoster during maintenance therapy.	Added consideration for prophylaxis for herpes zoster virus per current IB
23.	Section 2.6.2. Bortezomib	The most common bortezomib side effects include: … • Neuromuscular and skeletal: arthralgias, back pain, bone pain, muscle cramp and myalgias • Miscellaneous: rash, hemorrhage, blurred vision, deafness, hepatitis, hyperbilirubinemia	The most common bortezomib side effects include: … • Neuromuscular and skeletal: arthralgias, back pain, bone pain, muscle cramp and myalgias • Cutaneous: alopecia • Miscellaneous: rash, hemorrhage, blurred vision, deafness, hepatitis,	Added alopecia and peripheral edema risks per current IB

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			hyperbilirubinemia, peripheral edema	
24.	Section 2.6.7. Ixazomib	Please refer to the current MLN9708 (ixazomib) Investigator's Brochure (IB) and Safety Management Attachment (SMA). The most frequent AEs reported to date in the ongoing MLN9708 phase 1 studies were anticipated based on preclinical data and previous experience with bortezomib, and are noted in the IB, the SMA, and the informed consent documents (Appendix B).	Please refer to the current MLN9708 (ixazomib) Investigator's Brochure (IB). The most frequent AEs reported to date in the ongoing MLN9708 studies are noted in the IB and informed consent document (Appendix B).	Per pharmaceutical contributor, SMA is now incorporated within the IB
25.	Section 3.1. Definition of Disease Status, Very Good Partial Response (VGPR)	For free light chain only disease, VGPR requires a 90% reduction of involved light chain.	For free light chain only disease, VGPR requires a 90% reduction of involved light chain. For patients without measurable monoclonal paraprotein at the time of relapse or progression, VGPR requires a 90% reduction in the difference between involved and uninvolved free light chain level and <5% plasma cells in the bone marrow.	Added guidance for determining VGPR for patients with low burden of disease
26.	Section 4.1. Enrollment Procedures	An authorized user at the clinical center completes the demographics and primary eligibility screening forms, which	Enrollment onto the BMT CTN 1302 trial is a multi-step process and must be conducted by an authorized user at the clinical center.	Updated enrollment

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		include questions confirming that the patient signed the consent (Segment 0) and meets the eligibility criteria for study entry (Segment A). Once the patient is enrolled in the study (Eligibility Form, Segment A completed): 1. A visit schedule based on transplant date will be available for printing. 2. After the patient has adequately recovered from their Allogeneic Transplant, between 60 and 120 days post transplant, an authorized user at the clinical center completes a checklist confirming that the patient has recovered and is eligible to proceed to maintenance therapy. If the patient is eligible, they will be randomized to their treatment assignment and the treatment plan is continued (Eligibility Form, Segment B completed).	The following must be completed, in the below order, to enroll a patient onto trial: 1. Demographics Form 2. Segment 0 Enrollment Form – documents the patient's consent to participate in the trial 3. HLA Form – documents that the patient-donor HLA match score meets protocol requirements 4. Segment A Enrollment Form – documents that the patient meets the protocol's eligibility criteria (Section 2.3.1. through Section 2.3.3.) A patient is not considered enrolled onto the trial, thus no protocol-prescribed treatment can be initiated, until the Segment A Enrollment Form is successfully saved and a confirmation screen is provided indicating the enrollment was successful. Once the patient is enrolled, the Transplant Form must be completed in order to populate a visit schedule in the Forms Grid. After the patient has adequately recovered from their transplant, he or she will be screened for eligibility for the randomized maintenance portion of the trial. If the patient is found to be eligible, the Segment B Enrollment Form must be completed	procedures for clarity

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			between 60 and 120 days post-transplant to document that the patient meets the maintenance eligibility criteria (Section 2.3.4. through Section 2.3.5.). Successfully saving this form randomizes the patient. Maintenance study drug cannot be ordered until the Segment B Enrollment Form is completed and a confirmation screen with a randomization assignment is provided. Refer to the BMT CTN 1302 Forms Guide for further guidance on the enrollment procedures and forms completion.	
27.	Section 4.2.1. Follow-Up Schedule	A detailed description of each of the forms and the procedures required for forms completion and submission can be found in the Data Management Handbook and User's Guide.	A detailed description of each of the forms and the procedures required for forms completion and submission can be found in the BMT CTN 1302 Forms Guide.	DMH and User's Guide no longer in use
28.	Table 4.3.2. Patient Clinical Assessments for Randomized Patients (Pre/Post Maintenance)	[1] Weekly laboratory monitoring (± 2 days) is required during Cycle 1. Laboratory monitoring is required once every cycle for all other cycles.	[1] Weekly laboratory monitoring (± 2 days) is required during Cycles 1 and 2. Laboratory monitoring is required once every cycle for all other cycles.	Updated for accuracy
29.	Appendix B, 1. Introduction	You are between the ages of 18 and 65	You are at least 18 and no older than 70 years of age.	Expanded maximum eligible age to 70
30.	Appendix B, 2. Study Background	Your disease came back (relapsed) less than 18 months after an autologous transplant	Your disease came back (relapsed) less than 24 months after an autologous transplant	Extended time to progression

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31.	Appendix B, 6. Risks and Discomforts, Bortezomib	*Risk added*	*Added risk to **likely** column:* • hair loss	Updated per current IB
32.	Appendix B, 6. Risks and Discomforts, Bortezomib	Rash with skin peeling and mouth sores that can lead to death	Blistering rash with skin peeling and mouth sores that can lead to death	Updated per current IB
33.	Appendix B, 6. Risks and Discomforts, Ixazomib	*Likely risks column:* ▪ Low number of platelets in the blood with increased risk of bleeding ▪ Skin rash ▪ Feeling tired ▪ Feeling weak ▪ Fever ▪ Nausea and vomiting ▪ Diarrhea ▪ Constipation ▪ Pain, numbness and tingling in hands and feet ▪ Anemia (low number of red blood cells) ▪ Low number of white blood cells ▪ Infection ▪ Changes in the way food tastes ▪ Loss of appetite ▪ Trouble catching your breath ▪ Lung infection (pneumonia) ▪ Headache ▪ Cough ▪ Aches or pain in arm and leg muscles, joints, and bones	*Likely risks column:* ▪ Low number of platelets in the blood with increased risk of bleeding ▪ Skin rash ▪ Feeling tired ▪ Feeling weak ▪ Nausea and vomiting ▪ Diarrhea ▪ Constipation ▪ Pain, numbness and tingling in hands and feet ▪ Anemia (low number of red blood cells) ▪ Low number of white blood cells ▪ Infection ▪ Loss of appetite ▪ Lung infection (pneumonia) ▪ Muscle weakness ▪ Swelling of the hands, feet, ankles or lower legs ▪ Upset stomach or pain in the belly or back ▪ Low blood pressure	Removed risks per current IB

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		▪ Swelling of the hands, feet, ankles or lower legs ▪ Upset stomach or pain in the belly or back ▪ Low blood pressure and feeling dizzy ▪ Trouble sleeping		
34.	Appendix B, 6. Risks and Discomforts, Ixazomib	[1]Persons with a weakened immune system may develop PML, which can cause death or severe disability. One fatal case of PML has been reported in a patient outside of this study who had previously received ixazomib. It is not known if ixazomib may have contributed to the development of PML in this patient.	[1]PML has been observed rarely (< 0.1%) in patients taking ixazomib. It is not known if ixazomib may contribute to the development of PML in this patient.	Updated per current IB
35.	Appendix B, 10. Privacy, Confidentiality and Use of Information	Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. All your medical and demographic information (such as race and ethnicity, gender and household	Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to	Updated confidentiality language

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		income) will be kept private and confidential. *(Name of Transplant Center)* and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or regulatory agencies. Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing to participate, you consent to such inspections and to the copying of parts of your records, if required by these organizations. We may give out your personal information if required by law. If	others will not identify who you are. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. All your medical and demographic information (such as race and ethnicity, gender and household income) will be kept private and confidential. *(Name of Transplant Center)* and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or regulatory agencies. Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing	

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		information from this study is published or presented at scientific meetings, your name and other personal information will not be used.	to participate, you consent to such inspections and to the copying of parts of your records, if required by these organizations.	
36.	Appendix B, 10. Privacy, Confidentiality and Use of Information	This data bank can be accessed by you and the general public at www.ClinicalTrials.gov. Federal law requires clinical trial information for certain studies to be submitted to the data bank.	A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. Data regarding your clinical situation, including follow-up after 2 years, may be obtained from the CIBMTR, which captures information on all U.S. transplants.	Updated clinicaltrails.gov language and added language about CIBMTR data
37.	Appendix H, Table H-1 Known Anticipated Risks of Bortezomib by MedDRA System Organ Class, Observed Incidence, and Preferred Term	**Skin and Subcutaneous Tissue Disorders** *Very common* - rash	**Skin and Subcutaneous Tissue Disorders** *Very common* – rash, alopecia	Updated per current IB