Summary of Changes Page
BMT CTN 1205 Protocol Amendment #4 (Version 5.0)
Dated July 22, 2016

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

Section number and title in Version 4.0	Section number and title in Amendment (Version 5.0)	Original Text	Changed To	Rationale
Protocol Synopsis – Study Design	Protocol Synopsis – Study Design	The study will be conducted as a supplement to the BMT CTN 1101, 1203, and 1301 clinical trials. Note that the BMT CTN 0901 trial was removed as a parent trial due to its closure on April 18, 2014.	The study will be conducted as a supplement to the BMT CTN 1101 and 1301 clinical trials. Note that the BMT CTN 0901 trial and BMT CTN 1203 trial were removed as parent trials due to their closure on April 18, 2014 and May 13, 2016, respectively.	The BMT CTN 1203 trial completed enrollment and closed in May 2016.
Section 2.1.2. – Summary of the BMT CTN 1101, 1203, and 1301 Protocols	Section 2.1.2. – Summary of the BMT CTN 1101 and 1301 Protocols	Summary of the BMT CTN 1101, 1203, and 1301 Protocols	Summary of the BMT CTN 1101 and 1301 Protocols	The BMT CTN 1203 trial completed enrollment and closed in May 2016.
2.1.2.2. BMT CTN 1203 (GVHD	--	2.1.2.2. BMT CTN 1203 (GVHD Prophylaxis)	*Section was removed*	The BMT CTN 1203 trial

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Prophylaxis)				completed enrollment and closed in May 2016.
4.1. Approaching Patients, Eligibility Screening and Obtaining Consent	4.1. Approaching Patients, Eligibility Screening and Obtaining Consent	Subjects may be approached for enrollment on the ETRIC protocol once they have been identified as potential participants for the BMT CTN 1101, 1203, or 1301 studies. Note that the BMT CTN 0901 trial was removed as a parent trial due to its closure on April 18, 2014, and no further patients will be enrolled from this study.	Subjects may be approached for enrollment on the ETRIC protocol once they have been identified as potential participants for the BMT CTN 1101 or 1301 studies. Note that the BMT CTN 0901 trial and BMT CTN 1203 trial were removed as parent trials due to their closure on April 18, 2014 and May 13, 2016, respectively, and no further patients will be enrolled from these studies.	The BMT CTN 1203 trial completed enrollment and closed in May 2016.
5.1. Study Design for Randomized Study	5.1. Study Design for Randomized Study	The randomized study will test two interventions – the ETRIC consent form vs. the standard consent form for patients participating in the BMT CTN 0901, 1101, 1203, and 1301	The randomized study will test two interventions – the ETRIC consent form vs. the standard consent form for patients participating in the BMT CTN 1101 and 1301 studies. The BMT CTN 0901 trial and	The BMT CTN 1203 trial completed enrollment and closed in May 2016. The BMT

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		studies. The BMT CTN 0901 trial was a removed as a parent protocol for the BMT CTN 1205 study due to its closure on April 18, 2014. Those who enrolled in the BMT CTN 1205 prior to the BMT CTN 0901 closure will be included in the analysis.	BMT CTN 1203 trial were removed as parent protocols for the BMT CTN 1205 study due to their closure to accrual on April 18, 2014 and May 13, 2016, respectively. Those who enrolled in the BMT CTN 1205 prior to the BMT CTN 0901 and BMT CTN 1203 closures will be included in the analysis.	CTN 0901 trial closed in April 2014 but some language regarding it was inadvertently left in this section.
Appendix F – ETRIC Templates for Parent Studies	Appendix F – ETRIC Templates for Parent Studies	Note that the BMT CTN 0901 trial was removed as a parent trial due to its closure on April 18, 2014. The BMT CTN 0901 ETRIC is in Appendix G.	Note that the BMT CTN 0901 trial and BMT CTN 1203 trial were removed as parent trials due to their closure on April 18, 2014 and May 13, 2016, respectively. The BMT CTN 0901 ETRIC and BMT CTN 1203 ETRIC are in Appendix G.	The BMT CTN 1203 trial completed enrollment and closed in May 2016.
Appendix F – ETRIC Templates for Parent Studies	Appendix G – BMT CTN 0901 & BMT CTN 1203 Closure Details and ETRIC	*Sample ETRIC Informed Consent Template for the BMT CTN 1203 Study*	*Sample ETRIC Informed Consent Template for the BMT CTN 1203 Study*	The BMT CTN 1203 trial completed enrollment and

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				closed in May 2016, so the 1203 ETRIC was moved from Appendix F to Appendix G.
Appendix F – ETRIC Templates for Parent Studies Sample ETRIC Informed Consent Template for the BMT CTN 1301 Study	Appendix F – ETRIC Templates for Parent Studies Sample ETRIC Informed Consent Template for the BMT CTN 1301 Study	BMT CTN 1301, v2.0	BMT CTN 1301, v3.0	The BMT CTN 1301 trial amended the informed consent.
Appendix F – ETRIC Templates for Parent Studies Sample ETRIC Informed Consent Template for the BMT CTN 1301 Study	Appendix F – ETRIC Templates for Parent Studies Sample ETRIC Informed Consent Template for the BMT CTN 1301 Study	Table 1: Timeline of Exams After Your Transplant …Monitoring for CMV, EBV, and Toxoplasmosis…	Table 1: Timeline of Exams After Your Transplant …Monitoring for CMV, EBV…	The BMT CTN 1301 trial amended the informed consent.

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Appendix F – ETRIC Templates for Parent Studies Sample ETRIC Informed Consent Template for the BMT CTN 1301 Study	Appendix F – ETRIC Templates for Parent Studies Sample ETRIC Informed Consent Template for the BMT CTN 1301 Study	We'll take about 2 teaspoons (or 6 mL) before you begin the conditioning regimen for your transplant, and about 20 teaspoons (or 80 mL) at each time: 35 days, 100 days, 6 months, and 1 year after your transplant.	We'll take about 2 teaspoons (or 6 mL) before you begin the conditioning regimen for your transplant, and about 20 teaspoons (or 86 mL) at each time: 35 days, 100 days, 6 months, and 1 year after your transplant.	The BMT CTN 1301 trial amended the informed consent.
Appendix G: BMT CTN 0901 Closure Details and ETRIC	Appendix G – BMT CTN 0901 & BMT CTN 1203 Closure Details and ETRIC	Appendix G: BMT CTN 0901 Closure Details and ETRIC	Appendix G – BMT CTN 0901 & BMT CTN 1203 Closure Details and ETRIC	The BMT CTN 1203 trial completed enrollment and closed in May 2016.
Appendix G: BMT CTN 0901 Closure Details and ETRIC	Appendix G – BMT CTN 0901 & BMT CTN 1203 Closure Details and ETRIC	--	**BMT CTN 1203 CLOSURE DETAILS AND ETRIC** The BMT CTN 1203 study was a phase II, multicenter, randomized clinical trial investigating whether any of three new GVHD prophylaxis approaches improved the rate of GVHD and relapse free	The BMT CTN 1203 trial completed enrollment and closed in May 2016.

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			survival at one year after allogeneic transplant in patients with acute leukemia, chronic myelogenous leukemia, myelodysplasia, chronic lymphocytic leukemia/small lymphocytic lymphoma, follicular lymphoma, marginal zone lymphoma, Hodgkin's Lymphoma, diffuse large B cell lymphoma, or mantle cell lymphoma. The primary objective was comparison of one year GVHD/relapse or progression-free survival (GRFS) after hematopoietic stem cell transplantation (HSCT) between each of three novel GVHD prophylaxis approaches and a contemporary control from the Center for International Blood and Marrow Transplant Research (CIBMTR) database. Rates of grade II-IV and III-IV acute GVHD, visceral acute GVHD,	

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			chronic GVHD, immunosuppression-free survival at one year, hematologic recovery (neutrophil and platelet), donor cell engraftment, disease relapse or progression, transplant-related mortality, rates of Grade $\geq$ 3 toxicity according to the Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0, incidence of infections, immune reconstitution, and overall survival were secondary endpoints. The trial opened for enrollment on September 17, 2014 and closed to accrual on May 13, 2016. Approximately 100 potentially eligible 1203 patients enrolled onto the BMT CTN 1205 study between November 2014 and May 2016. Table G-2 outlines the patient reported assessments for the 1205 and 1203 studies.	

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			Table G-2: Patient Assessments in the BMT CTN 1205 and 1203 Studies	