

## Summary of Changes to the CEA Protocol for BMT CTN 1101

Protocol Version 4.0 dated December 15, 2015

1. Cover page – changed CEA protocol version to 4.0, dated December 15, 2015
2. Cover page - removed Mark Bensink and David Blough as CEA Study Investigators
3. Table of Contents (page v) – the titles in the list of appendices have changed as follows:
  - Appendix B has changed to include the HIPAA Authorization Form in addition to the patient informed consent that was previously listed
  - Appendix C has changed to remove confidential health insurance information since this is now covered by the HIPAA Authorization Form in Appendix B. The Appendix C form now only collects patient and caregiver contact information
4. Section 4.1.2, Page 8 of Enrollment Procedures – the instructions have changed as follows:
  - Item a – the study coordinator will complete the HIPAA Authorization Form and the Patient Consent Form as part of Appendix B
  - Item b – the confidential health insurance language has been removed from Appendix C (since this language is covered by the HIPAA Authorization Form), and is now limited to collecting patient and caregiver contact information
  - Item c – clarifies that if a patient nominates a caregiver who is not accompanying the patient, that the FHCRC team will mail the Caregiver Consent Form or call the caregiver to determine whether the caregiver is interested in participating
  - Item d (top of page 9) – language has been added to clarify that the Patient Consent Form for the CEA substudy must also be copied and kept on file by the transplant coordinator
  - Item f (page 9)– the list of items to be faxed have been updated for consistency
5. Section 4.1.3b, Page 9 – the Named Caregiver Informed Consent has been changed from Appendix C → Appendix D for accuracy
6. Appendix B – addition of the HIPAA Authorization Form with fields for collecting health insurance information
7. Appendix C – removal of “Confidential Health Insurance Information” from the Appendix C title since this information is now included in the HIPAA Authorization Form in Appendix B. The health insurance information fields have also been removed since this data is now collected on the HIPAA Authorization Form. The Appendix C form is now restricted to collecting patient and caregiver contact information.