

PROTOCOL SYNOPSIS – BMT CTN PROTOCOL 1205**Easy-to-Read Informed Consent (ETRIC) for
Hematopoietic Cell Transplantation Clinical Trials**

- Study Chairs:** Navneet S Majhail, M.D., M.S.
Ryan Spellecy, Ph.D.
- Study Design:** This 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 study has two parts:
- (1) **Randomized Study:** Randomized, multicenter, prospective comparative study of ETRIC or standard consent form to improve patient comprehension of BMT CTN parent clinical trials. Patients who are being considered for one of the clinical trials will be approached, and on providing verbal consent to 1205, will be randomized to and will undergo the consent process for the parent trial using either ETRIC or standard consent form. Assessments will be conducted for patient comprehension of the clinical trial and satisfaction and anxiety related to the consent process.
 - (2) **Evaluation Study:** To understand barriers to implementation of ETRIC, site visits to 9 transplant centers participating in the BMT CTN parent studies will be conducted with semi-structured interviews of IRB administrators, site protocol investigators, and study coordinators. Sites will include centers that are participating and are not participating in the ETRIC study.
- Primary Objective:** Primary objective of the randomized study is to compare objective comprehension scores on the Quality of Informed Consent (part A) instrument between patients randomized to the ETRIC versus the standard consent arms.
- Secondary Objectives:** Secondary objectives of the randomized study are to compare the following measures between the two arms: (1) subjective comprehension scores on the Quality of Informed Consent (part B) instrument and the modified Deaconess Informed Consent Comprehension Test instrument, (2) state anxiety scores on State Trait Anxiety Inventory instrument, (3) satisfaction scores, (4) time taken for information location, and (5) patient consent rates on parent clinical trials.
- Eligibility:** Inclusion and exclusion criteria for the ETRIC study will be the same as the eligibility criteria for the BMT CTN parent studies. Additional inclusion criterion specific for the ETRIC study will include:

1. Adult patients (≥ 18 years)
2. Speaking and reading proficiency in English
3. Willing and able to provide informed consent for the ETRIC study
4. Stated willingness to comply with study procedures and reporting requirements

Study Interventions: Each ETRIC form for the parent protocols will have a two-column format with specific attention towards enhancing readability and processability including layout, organization of content, typography, and using plain language.

The standard consent form for the parent protocols will have a single column format and will lack the formatting and readability enhancements of the ETRIC form.

The content of both forms will be similar and both will contain all federally required elements for informed consent. Individual clinical trial sites will be allowed to make modifications to the ETRIC and the standard consent forms to meet requirements of their local IRBs. The protocol team will ensure that any such modifications to the ETRIC form conform to the easy-to-read format.

Accrual Objective: 198 patients will be randomized 1:1 between the two study arms for the randomized study.

Accrual Period: 3 years for the randomized study.

Study Duration: For the randomized study, assessments will occur within 7 business days of the consent discussion for the parent studies. No subsequent patient followup is planned for this study.

Statistical Issues: For the randomized study, patients will be randomized 1:1 between the ETRIC and standard consent arms. A total of 198 patients will be accrued in this study (99 in each arm), which will allow detection of a 0.5 standard deviation difference with 80% power in the mean Quality of Informed Consent part A comprehension scores between the two study arms.