Full Protocol Title	A Randomized Recruitment Intervention Trial
Acronym (if appropriate)	RECRUIT
Clinical Trial Phase	Phase III
Study Sites	Up to 20 BMT CTN Sites with 25% or more total minority population within a 30 mile radius.
Study Period	Planned subject enrollment period – 2-3 years Planned duration of the study – 5 years
Study Population	BMT CTN Clinical trial site investigators and coordinators.
Primary Objective	The goal of RECRUIT is to help BMT CTN clinical trial site investigators and coordinators increase enrollment of minority subjects into the selected BMT CTN trials (1203, 1301, and 1302). Primary Specific Aim: Test an intervention targeting clinical trial site investigators and coordinators to increase subject diversity in multi-site treatment trials for diseases that require physician referral. H_{1a}: The proportion of racially/ethnically diverse participants (other than European Caucasian) enrolled in the intervention sites will be greater than the proportion enrolled in the control sites. Secondary Aim: To compare intervention and control sites on the number of referrals from community physicians, mean potential and enrolled participant satisfaction scores, and numbers and types of recruitment activities. H_{2a}: The number of referrals to the trial sites from community physicians will be greater in the intervention sites than in control sites; H_{3a}: Potential (screened) and enrolled participant satisfaction with clinical trial site investigators, and coordinators will be greater in the intervention sites than in control sites; H_{4a}: The numbers and types of activities related to activities encouraged through the trial training program and reported on recruitment activity logs will be greater in the intervention sites than in control sites.
Background	The lack of minority participation in clinical trials is a long-standing problem. This lack of diversity in clinical trial participation is a barrier to the development of new therapies because of potential racial/ethnic differences in response to treatment. Very little rigorous research has been conducted regarding approaches to increasing subject diversity in clinical trials. Therefore we are conducting a randomized trial of a

	recruitment intervention trial (RECRUIT) to increase minority participation. This trial is testing an enhanced training program based on what was learned from a previous recruitment trial, the literature, and on an intervention mapping strategy to improve and enhance implementation of a recruitment program to increase subject diversity in clinical trials that require physician referrals.
Study Design	This is a randomized Phase III trial of a recruitment intervention with clinical trial site as the unit of randomization.
Inclusion Criteria	Inclusion Criteria: In order for the BMT CTN trials to be included the BMT CTN Coordinating Center must be willing to allow their Clinical Sites to participate; The BMT CTN trial must • be studying a less common disease/condition, i.e., prevalence approximately <5% in the age group of interest or be studying a condition that requires physician referral • be studying an intervention where the recruitment approach cannot be made directly to minority community members • need to increase recruitment of racially/ethnically diverse subjects to the trial as demonstrated by current trial progress or historical data from other trials in the same disease; • be a Phase II or Phase III trial • be conducted in at least six multiple sites; • expect each Clinical Site to recruit at least 6 to 10 subjects; • be funded by a sponsor (NIH or pharmaceutical company or other) that has a strong commitment to recruiting racially/ethnically diverse subjects; • be willing to have investigators and coordinators in the intervention group attend a special training meeting (at RECRUIT expense); • require subject randomization to intervention or control (could be best medical care or active control or placebo or other type of control); • provide transportation costs for trial subjects who need assistance in getting to trial sites or use some RECRUIT reimbursement for this purpose.
Exclusion Criteria	Clinical Site Exclusion Criteria: • Clinical site refuses to be randomized. • Clinical site has less than 25% minorities living within 30 miles of the site.
Study Intervention and Duration	Eligible BMT CTN sites will be randomized to the intervention or control group after signing a RECRUIT Consent form. The RECRUIT Consent form was approved by the University of Texas Health Science Center IRB.

	Intervention group: BMT CTN site investigators and coordinators will receive the educational recruitment program. These sites will work with the RECRUIT team to enhance and individualize their recruitment methods. The site PI and coordinator will attend an in person kick off meeting to receive training on minority recruitment strategies and attend 4-5 one hour training webinars (approximately 1/month). The coordinators will also participate in short monthly recruitment follow up calls with a RECRUIT team member. Control group: BMT CTN sites will follow planned recruitment practices. The site PI and coordinator will attend a 45 minute webinar to learn about the data collection efforts for RECRUIT at their site. All sites participating in RECRUIT will send non-PHI screening logs and recruitment activities checklist to the RECRUIT Coordinating Center monthly. Distribute anonymous satisfaction surveys to all subjects screened and/or enrolled for the selected BMT CTN trials. RECRUIT will collect recruitment data until the sites have completed recruitment for the selected BMT CTN trials or for approximately 2 years. All site principal investigators and coordinators participating in RECRUIT must complete a brief demographics form and complete a telephone interviews at the end of the RECRUIT study.
Primary Outcome Measure	Percent of minority subjects enrolled in intervention and control trial sites. Will be measured by subject enrollment data provided by the BMT CTN Coordinating Center.
Sample Size	60 Clinical sites (from multiple trials) Assumes 10% difference from control is clinically meaningful; 30 intervention and 30 control sites; approximately 10 subjects per site; two-sided alpha = 0.05. Assumes within site correlation, rho of 0.1.
Statistical Analysis for Primary Outcome Measure	We will describe the distributions of the response outcomes and the sample characteristics by treatment group, and other baseline characteristics. As the primary analysis comparing sites on proportion of diverse subjects recruited we will use a generalized linear mixed model (GLMM) with logit link to account for clustering by site. Depending on the number of investigators/site we may need to adjust for clustering within physician as well.