



BMT CTN PROPOSED NEW STUDY CONCEPT FORM

Principal Investigator:

Phone number:

Email Address:

Institution:

Title of Protocol:

Preliminary Data and Background:

Primary Hypothesis:

Secondary Hypothesis(es):

Patient Population (include type of disease(s), age range, and basic eligibility criteria):

Treatment Plan (include type of transplant(s), conditioning therapy, GVHD prophylaxis and experimental treatment agent if applicable):

Primary Outcome:

Secondary Outcome(s):

Potential laboratory/QOL/Ancillary Studies:

Basic Study Design:

Phase: ☐ I ☐ II ☐ III ☐ Other

Blinded: ☐ Yes ☐ No

Randomized: ☐ Yes ☐ No

Accrual Period:

Follow-up Period:

Sample Size (provide details of computation, i.e., detectable difference, power and size):

Requires IND/IDE: ☐ Yes ☐ No

If yes, please indicate status of preparation, submission and approvals for regulatory documents:

Requires central pharmacy: ☐ Yes ☐ No

Special specimen collection considerations: ☐ Yes ☐ No
If yes, specify:

Potential for supplemental funding:

Potential for Cooperative Group involvement:

- ☐ Alliance
- ☐ SWOG
- ☐ COG
- ☐ ECOG-ACRIN
- ☐ Other:

Additional Comments: