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: