# 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:**