**BMT CTN Ancillary Study Proposal Utilizing Biospecimens**

Investigators are requested to provide a thorough, yet concise response to each section of the proposal. A complete, well-developed proposal will greatly facilitate the timeliness of your proposal’s review by BMT CTN Protocol Teams, DCC and Executive Committee members. Additionally, having sufficient information will assist the BMT CTN in the assessment of biospecimen and clinical data availability, and in the accurate evaluation of your study proposal objectives, feasibility, study design and scientific merit.

Investigators should allow a minimum of 30 business days for the appropriate teams and committees to complete their review and to provide a final determination regarding study approval.

Please submit completed proposals to the following BMT CTN DCC contacts:

Valerie Stewart ([vstewar2@nmdp.org)](mailto:vstewar2@nmdp.org)Y) or Yung-Tsi Bolon ([ybolon@nmdp.org)](mailto:ybolon@nmdp.org))

**PI Information:**

|  |  |
| --- | --- |
| PI Name (First, Middle, Last): |  |
| Institution Name: |  |
| Title: |  |
| Phone: |  |
| Email: |  |

**Co-Investigators (if applicable):**

**Title of Laboratory Study**:

**BMT CTN Protocol(s) Associated with Study:**

**Specific Study Aims**:

**Preliminary Data and Background**:

**Study Eligibility: (***Eligible population for the ancillary study. Specify if this study applies to all patients enrolling on the parent trial or limited to a subgroup. Please provide a brief statistical justification for the number of subjects and research samples that need to be included on the proposed study. The justification for these samples, planned analyses, and relationship of samples to clinical endpoints should be clearly presented*

**Biospecimens Required and Time Points**: **(***Please be specific in indicating the sample type(s) that can be used for your study; such as EDTA plasma, heparin plasma, serum. Also, please indicate the minimum sample volume that could be used to complete the testing described in your study.***)**

**Summary of Methods**:

**Clinical Outcomes Data Required for Study Analysis**:

**Study Analysis Plan & Statistician Support**: **(***Please provide sufficient information to show that a thorough study analysis plan has been developed in the context of all study aims. Please provide names and qualifications related to this study for any co-investigators providing statistical support for the study analysis. If BMT CTN statistical support is desired for this study, please clearly indicate this request in your study proposal. You will be contacted by a BMT CTN DCC representative to discuss your request and determine if resources are available to support your study***)**.

**Funding for this Ancillary Laboratory Study**:

Funds are currently available **(Yes/No)**:

If Yes, from where, and what is the amount available?

If No, how do you plan to fund the study?

\_\_\_\_\_I plan to apply for funding through my institution.

**(Please give specifics)**:

\_\_\_\_\_I plan to apply for funding in collaboration with other investigators.

**(Please give specifics)**:

\_\_\_\_\_I plan to apply for funds from **(complete)**:

**References**: