**BMT CTN Ancillary Study Proposal**

An **ancillary study** entails the collection from study participants of data and/or specimens, or the conduct of additional analyses of existing materials or samples that are outside the specific objectives of the primary study. A **secondary data analysis** uses previously collected data from BMT CTN studies to look at objectives other than those addressed in the original studies.

Investigators are requested to provide a thorough yet concise response to each section of the Non-Primary Study Proposal. A complete, well-developed proposal will improve the timeliness of proposal review by BMT CTN Protocol Teams, Data Coordinating Center (DCC), and Executive Committee. Additionally, providing sufficient information will assist the BMT CTN in the assessment of biospecimen and clinical data availability and in the accurate evaluation of the study proposal’s objectives, feasibility, 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** **bmtctn\_nmdp@nmdp.org****.**

For inquiries, please contact Valerie Stewart (vstewar2@nmdp.org).

**PI Information:**

PI Name (First, Middle, Last):

Institution Name:

Title:

Phone:

Email:

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

**Title of Study**:

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

**Type of Study:**

[ ] Ancillary study utilizing biospecimens

[ ]  Secondary data analysis

**Specific Study Aims:**

**Preliminary Data and Background**:

**Study Eligibility:** *Please indicate the eligible population for the study, specifying both inclusion and exclusion criteria. Specify whether the study includes all patients enrolled on the parent trial(s) or is limited to a subset. Provide a thorough yet concise statistical justification (power calculation) for the number of subjects to be included in the proposed study*.

**Biospecimens Required: *Ancillary studies only*.** *Please indicate the* ***sample type(s)*** *that can be used for your study (EDTA plasma, heparin plasma, serum, etc.) and the* ***time points*** *required per patient. Also, please indicate the* ***minimum sample volume*** *that could be used to complete the testing described in your study.*

**Summary of Methods**: ***Ancillary studies only.***

**Clinical Outcomes Data Required:** *Please specify the patient characteristics, data elements, and outcomes data required for study analysis.*

**Anticipated Study Timeline:** *Please indicate the desired timeframe for distribution for biospecimens and/or clinical data.*

**Dataset Format:** *Data is provided in both Excel and SAS formats. Please specify other requirements as needed, indicating ‘****None****’ if no additional format is required*.

**Data Sharing Mechanism:** *Data is provided via secure mechanism such as sFTP (Emmes), BOX (MCW), or VDR through Outlook Sharepoint (NMDP). Please specify any additional requirements, indicating ‘****None****’ if no alternate delivery method is required*.

**Statistical Analysis Plan:** *Please provide sufficient information to show that a thorough study analysis plan has been developed in the context of all study aims and hypotheses*.

**Statistician Support:** *Please indicate whether BMT CTN statistician support is requested for study analysis, aside from provision of the primary trial dataset.*

[ ] **Yes***, BMT CTN DCC statistician support is required to perform the analysis.*

***Please clearly describe the request in the proposal and a BMT CTN DCC representative will be in contact to discuss the request and determine whether resources are available to support the study.***

[ ]  ***No,*** *I only need data support (i.e. primary trial dataset) from BMT CTN DCC.*

***Please provide names and qualifications of all investigators providing statistical support for the study analysis:***

**Study Funding:**

Please indicate whether funds are currently available:

[ ]  ***Yes***

***Please indicate funding source and amount available:***

[ ]  ***No***

 ***Please the anticipated source of study funding:***

[ ]  I plan to apply for funding through my institution.

 ***Please specify****:*

 [ ]  I plan to apply for funding in collaboration with other investigators.

***Please specify****:*

 [ ]  I plan to apply for funds from **(complete)**:

**References:**

**Notes on Funding**

* Funding is required for dataset provision regardless of whether analysis will be conducted by a BMT CTN DCC statistician. Cost is estimated based on the data request (e.g. number of protocols, variables, etc.)
* Additional and separate funding will be required if BMT CTN DCC staff are requested to perform statistical analysis for the secondary study.
* An approved project for which funding has not been secured must be re-reviewed by the BMT CTN Executive Committee no later than 18 months from the date of proposal approval.

**NHLBI BioLINCC Data Repository Information Center**

All BMT CTN studies (if applicable) submit final data to NHLBI BioLINCC after the completion/publication of the study. The BioLINCC team manages the fulfillment of BMT CTN clinical data requests for secondary data analyses for future researchers. Resources managed by BioLINCC can be accessed using the links provided below. This process involves provision of basic information surrounding the request and upload of the study proposal. Requests are reviewed by the NHLBI Scientific Review Committee whose final approval is required for release of trial data. Data transfer and support for approved proposals is provided directly by the BioLINCC team. Please note that BioLINCC data uses randomized subject IDs, thus BioLINCC datasets might not readily link to non-BioLINCC datasets or specimens.

**BioLINCC Account Registration** (*required to request BIOLINCC resources*):<https://biolincc.nhlbi.nih.gov/register/>

**Study Data Resource Description, Materials, and Data Requests** (*search by keyword or study ID*): <https://biolincc.nhlbi.nih.gov/studies>