# Application for Participation as an Affiliate Center in the BMT CTN

BMT CTN Protocol Number:

Protocol Title:

Center Name:

Center Address:

CIBMTR Center Number/CNN (If applicable):

**Principal Investigator Information:**

Name:

Phone:

Email:

Address:

**Application Submitted by:**

Name:

Title:

Phone:

Email Address:

Date Submitted:

**The protocol is available on the BMT CTN public website at www.bmtctn.net. Please review the protocol thoroughly before completing this application.**

1. What is your projected annual accrual for this protocol? _____ patients per year
2. Will your center be including pediatric patients?
   - ☐ Yes
   - ☐ No
   - ☐ N/A
3. How many total active IRB-approved transplant research protocols are currently open at your site:

4. Does your center have any active IRB-approved protocols that will compete against this BMT CTN protocol?
   - ☐ Yes
   - ☐ No

   If Yes, provide a brief description of each competing protocol and explain how your center will prioritize studies:

5. What is the estimated time frame from when the protocol is released to your center to first patient enrolled?

   _____ months

**If your center has accrued patients on a BMT CTN study in the past 3 years, the application is complete. Please email to BMT CTN Data and Coordinating Center at bmtctnac@emmes.com**

**If your center has never participated on a BMT CTN study or has not accrued patients on a BMT CTN study in the past 3 years, please complete the remainder of the application.**

**Minimum Qualifications as a BMT CTN Affiliate Center are "Yes" to one of questions #6, 7 or 8**

6. Is your center an NMDP participating center?
   - ☐ Yes
   - ☐ No

7. Is your center FACT accredited?
   - ☐ Yes
   - ☐ Yes pending; date completed:
   - ☐ No

8. Is your center an approved NCTN Cooperative Group transplant center?
   - ☐ Yes
   - ☐ No

   If Yes, CTEP Site Code:

   Which group:
   - ☐ SWOG
   - ☐ Alliance for Clinical Trials in Oncology
   - ☐ ECOG-ACRIN
   - ☐ COG

9. Is your center a CIBMTR participating center?
   - ☐ Yes
   - ☐ No

   If Yes, CIBMTR Center Number (CCN):

   If Yes, does your center submit data on (check all that apply)
   - ☐ Allogenic Transplants
   - ☐ Autologous Transplants
   - ☐ Cellular Therapy

10. Please complete the below table documenting your transplant center's activities.

**NOTE:** Please complete the graft source table if your center does NOT submit data to the CIBMTR. If your center submits all transplants/cellular therapies data to CIBMTR, you do not need to complete the table (but please verify your center's CIBMTR data submission is up to date)

Twelve Month Period: _____ through _____
Month/Year Month/Year

| | Autologous | HLA-identical Sibling | Haplo-identical Donor | Unrelated Donor | Cord Blood | Cellular Therapy |
|---|---|---|---|---|---|---|
| AML | | | | | | |
| ALL | | | | | | |
| CML | | | | | | |
| MDS | | | | | | |
| Other Leukemia | | | | | | |
| MPS | | | | | | |
| Follicular NHL | | | | | | |
| Diffuse Large Cell NHL | | | | | | |
| Other NHL | | | | | | |
| Hodgkin Disease | | | | | | |
| Multiple Myeloma | | | | | | |
| Neuroblastoma | | | | | | |
| Breast Cancer | | | | | | |
| Other Solid Tumor | | | | | | |
| Aplastic Anemia | | | | | | |
| Immune Deficiency | | | | | | |
| Inborn Errors or Metabolism | | | | | | |
| Autoimmune Disease | | | | | | |
| Other, Specify: | | | | | | |
| | | | | | | |

11. Does your center agree to submit a Comprehensive Report Form level data to CIBMTR on all patients enrolled in a BMT CTN trial and TED level data for all transplant patients at your center whether or not they are enrolled in a BMT CTN study, during the period you are actively enrolling patients as an Affiliate Center?
    - ☐ Yes
    - ☐ No

**Please Note: All CIBMTR participating centers must submit a Comprehensive Report Form unless otherwise noted for any patient participating in a BMT CTN trial regardless of your center's status for CIBMTR data.** A copy of CIBMTR data collection forms can be found here: https://www.cibmtr.org/DataManagement/DataCollectionForms/pages/index.aspx

12. Is your center enrolled in the NMDP single IRB?
    - ☐ Yes
    - ☐ No

    If no, enrollment in the NMDP single IRB is required for participation and will require a separate reliance agreement, will your institution allow the use of the NMDP single IRB?

    - ☐ Yes
    - ☐ No

13. Please list number of research staff whose job functions are related to transplant:

| Staff Title | Total Full-Time Equivalents (FTEs) |
|---|---|
| Protocol Nurse | |
| Regulatory Coordinator | |
| Data Manager | |
| Other, Specify: | |

14. Has your research office ever been audited by the FDA?
    - ☐ Yes; Date(s):
    - ☐ No

## Investigational Research Pharmacy

15. Does your institution have a pharmacy that is able to receive, store and dispense investigational drugs and maintain appropriate documentation?
    - ☐ Yes
    - ☐ No

16. Please indicate the controlled drug storage temperatures available in your IDS Pharmacy.

    _____ Controlled Ambient

    _____ Controlled Refrigerated

    _____ Controlled Frozen

17. Does your center and Investigation Drug Services (IDS) Pharmacy have the capability of preparing and infusing investigational drugs on weekends?
    - ☐ Yes
    - ☐ No

18. Does your IDS Pharmacy have an SOP for the destruction of remaining study drug at the end of the study?
    - ☐ Yes
    - ☐ No

## Research Samples

19. Does your center have the ability to collect and promptly process research specimens (e.g., centrifuge blood tubes and prepare plasma or serum aliquots)?
    - ☐ Yes
    - ☐ No

    If Yes, is this service available for study visits falling on weekends?
    - ☐ Yes
    - ☐ No

20. Does your center have appropriate freezer storage for short-term storage of frozen plasma or serum cryovials that will be periodically batched-shipped to a project laboratory or BMT CTN Biorepository?

    ☐ Yes
    - Storage at -20°C available _____
    - Storage at -70 to 80°C available _____

    ☐ No

21. Does your center allow remote monitoring and access to your Electronical Medical Record (EMR)?

    ☐ Yes
    ☐ No

**Please email completed application to BMT CTN Data and Coordinating Center at bmtctnac@emmes.com**