



## **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](http://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](mailto: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

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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](mailto:bmtctnac@emmes.com)**