CIBMTR New Center Questionnaire

Organization Information

The following pages are designed to gather the information that the CIBMTR needs to begin setting up your organization as a CIBMTR center. Please answer all applicable questions as completely as possible.

Please enter your email below. When the questionnaire is complete, you will receive a copy of your response by email:*  
_________________________________________________

Where is your organization located?
( ) In the United States
( ) Outside of the United States
( ) Multi-national with some branches in the United States, some in other countries

Organization Name*: _______________________________________________________

Department or Program Name (if applicable): _______________________________________

Street Address: _______________________________________________________________

Apt/Suite/Office: _______________________________________________________________

City: ________________________________________________________________

State: ________________________________

Zip: ________________________________

Website: ________________________________________________________________

About Your Organization

Are you requesting a new CIBMTR center number for a treatment unit associated with a current CIBMTR member or a hospital system with at least one network hospital as a current CIBMTR member?
( ) Yes
( ) No
( ) I need additional information

Which CIBMTR member center(s) are you affiliated with?
Please explain what type of information you would like.

_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________
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Has your organization worked with CIBMTR (including ABMTR, IBMTR or NMDP) in the past?
( ) Yes
( ) No
( ) Unknown

Please indicate your former center number, if known: ________________

Please indicate when your center was last active (month and year), if known.
_________________________________________________

Center Activity Information

Patient type (s)
( ) Pediatric
( ) Adult
( ) Both

Infusion types performed at your organization (please check all that apply)
[ ] Autologous hematopoietic cell transplant
[ ] Allogeneic hematopoietic cell transplant, related
[ ] Allogeneic hematopoietic cell transplant, unrelated
[ ] Other autologous cellular therapies
[ ] Other allogeneic cellular therapies
[ ] Gene therapies
[ ] Other cellular therapies
[ ] Other - please specify:: _______________________________________________
There are two types of forms submitted for hematopoietic cell transplants - Transplant Essential Data (TED) and Comprehensive Report Forms (CRF.) Reporting level refers to the type of forms your organization chooses to complete. For each transplant type it is possible to choose a different reporting level. The CRFs are reimbursed according to our current Fee Schedule see current rates.

For Autologous HCT, which would your center prefer?
( ) Do Transplant Essential Data forms for all patients
( ) Do Comprehensive Research Forms for some and Transplant Essential Data forms for others based on an algorithm

For Allogeneic, related HCT, which would your center prefer?
( ) Do Transplant Essential Data forms for all patients
( ) Do Comprehensive Research Forms for some and Transplant Essential Data forms for others based on an algorithm

For Allogeneic, unrelated HCT, which would your center prefer?
( ) Do Transplant Essential Data forms for all patients
( ) Do Comprehensive Research Forms for some and Transplant Essential Data forms for others based on an algorithm

Cellular Therapy

CIBMTR is now asking for a cellular therapy reporting preference for each site. Reporting preference refers to the types of cellular therapy infusions reported to CIBMTR. One option must be selected.

Please do not include Donor Cellular/Donor Lymphocyte Infusions (DCI/DLI) as a type of cellular therapy

Examples of cellular therapy include, but are not limited to, CAR-T, Tumor-Infiltrating Lymphocytes (TILs), Virus-specific T-cells (VSTs) and Cytotoxic T-cells (CTLs)

Definitions:

Do Not Perform
- Site does not perform any cellular therapy infusions, only HCT
  - Please note, if your site performs DCI/DLIs, please exclude them

Perform Do Not Report
- Site is performing cellular therapies (i.e. CAR-T), but no infusions are submitted to CIBMTR
  - Please note, if your site performs DCI/DLIs, please exclude them

Research Level
- All cellular therapy infusions that are performed at the site are submitted to CIBMTR
  - This include all commercially available products, investigator studies and clinical trial infusions.

Regulatory Level
- ONLY Commercially available cellular therapy infusions are submitted to CIBMTR
  - Examples include Kymriah®, Yescarta®, Tecartus™, Breyanzi™
Please select one of the following options to describe the cellular therapy reporting your center would like to do:

( ) Do not perform
( ) Perform do not report
( ) Research Level
( ) Regulatory Level

Center Associations and Reference Numbers

Is your organization associated with an NMDP transplant center?
( ) Yes
( ) No

NMDP TC number: __________________________________________

Is your organization a member of The European Society for Blood and Marrow Transplantation (EBMT)?
( ) Yes
( ) No

EBMT CIC number: __________________________________________

Is your organization a member of The Asia Pacific Blood and Marrow Transplantation (APBMT)?
( ) Yes
( ) No

APBMT number: __________________________________________

Is your organization a member of the World Marrow Donor Association (WMDA)?
( ) Yes
( ) No

WMDA number: __________________________________________

Other reference number:
What is the name of the other organization and the reference number you would like us to have on record?

Organization: _________________________________________________
Number: _________________________________________________

Does your organization currently report clinical trial data to the National Cancer Institute’s Community Oncology Research Program (NCORP)?
( ) Yes
( ) No

Does your organization engage in other clinical research?
( ) Yes
( ) No

Please briefly describe other research.
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Has your organization participated in research that requires collection of blood and/or tissue samples?
( ) Yes
( ) No

Is your organization currently submitting data to a local or international outcomes registry?
( ) Yes
( ) No

Which other registry? (Check any that apply)
[ ] APBMT
[ ] EMBMT
[ ] EBMT
[ ] LATMO
[ ] SBTMO
[ ] Other: _________________________________________________
Staff Resources and Medical Records

Does your organization have available staff resources to enter outcomes data into FormsNet3℠, the CIBMTR's data capture system?

( ) Yes
( ) No

Is your data management staff able to report data in the English language?

( ) Yes
( ) No

Does your organization use an electronic medical records (EMR) or electronic health record (EHR) system?

( ) Yes
( ) No

Please select any applicable system(s) below or choose "Other" if not found.

[ ] Allscripts
[ ] Athenahealth
[ ] Care360
[ ] Cerner
[ ] eClinicalWorks
[ ] Epic
[ ] GE Healthcare
[ ] McKesson
[ ] OPTUMInsight
[ ] Practice Fusion
[ ] Other

What is the name of the EMR/EHR system used by your organization?

_________________________________________________

What language(s) are your organization’s paper records, EMR or EHR written in? Please select all that apply and/or select "Other" to type in additional language(s).

[ ] Arabic
[ ] Bengali
[ ] English
[ ] French
Which other language(s)?

_________________________________________________

Does your organization permit remote access to EMR or EHR for auditing purposes?
( ) Yes
( ) No

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Key Personnel

The CIBMTR may share your contact info with our non-profit research partners (such as ASTCT, NMDP, etc.) upon request, but will not share or sell email addresses to other industry partners.

Who will be the medical director at your site?

First Name: _________________________________________________

Last Name: _________________________________________________

Degree: _________________________________________________

Title: _________________________________________________

Email Address: _________________________________________________

Phone Number (include extension if applicable): _________________________________________________

Fax Number: _________________________________________________

Mobile Phone: _________________________________________________

Does the medical director have a different address than the organization?
What is the medical director’s address?

Street Address: _________________________________________________
Apt/Suite/Office: _________________________________________________
City: _________________________________________________
State: _________________________________________________
Zip: _________________________________________________

Is there an administrative support person we should have on record for your medical director?
( ) Yes
( ) No

Please provide information about the administrative support person.

First Name: _________________________________________________
Last Name: _________________________________________________
Title: _________________________________________________
Email Address: _________________________________________________
Phone Number: _________________________________________________
Fax Number: _________________________________________________

Who will be the primary data manager at your site?

First Name: _________________________________________________
Last Name: _________________________________________________
Degree and/or Certification: _________________________________________________
Title: _________________________________________________
Email Address: _________________________________________________
Phone Number (include extension if applicable): _________________________________________________
Fax Number: _________________________________________________

Mobile Phone: _________________________________________________

Does the primary data manager have a different address than the organization?
( ) Yes
( ) No

What is the primary data manager’s address?
Street Address: _________________________________________________
Apt/Suite/Office: _________________________________________________
City: _________________________________________________
State: _________________________________________________
Zip: _________________________________________________

Who will be the person designated to work with CIBMTR while your organization is being set up as a CIBMTR center?
First Name: _________________________________________________
Last Name: _________________________________________________
Title: _________________________________________________
Email Address: _________________________________________________
Phone Number: _________________________________________________

IRB – U.S. Centers Only

Does your center have a local institutional review board (IRB) or ethics committee that reviews human subject research?
( ) Yes
( ) No

The CIBMTR has a central IRB through the National Marrow Donor Program (NMDP) that may review and approve this research at your center. If you have a local IRB, your local IRB may delegate its oversight to the NMDP IRB. Utilizing the NMDP IRB will likely reduce the time your center spends on study administration, since CIBMTR staff are
responsible for most NMDP IRB submissions for this research. Is your center interested in using the NMDP IRB to review and approve this research?

( ) Yes
( ) No
( ) Unsure – I would like more information before deciding

Who is the main contact at your center responsible for IRB or regulatory submissions?

First Name: _________________________________________________
Last Name: _________________________________________________
Title: _________________________________________________
Email Address: _________________________________________________
Phone Number: _________________________________________________

Business and Finance

Does your center have a business or legal office contact who is responsible for contractual review? If so, please provide the contact information where contracts should be sent.

First Name: _________________________________________________
Last Name: _________________________________________________
Title: _________________________________________________
Email Address: _________________________________________________
Phone Number: _________________________________________________

Do you have any questions or comments for CIBMTR?

_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________
Thank You!

Thank you for providing the information we need to begin setting up your organization as a CIBMTR center. The next steps are:

- A CIBMTR center number (CCN) will be issued and sent to center contacts
- The Contracts department will contact you about the data-sharing agreement
- The Regulatory staff will contact you regarding IRB set up if you are wholly or partially located in the United States

If you have questions at any time during the setup process prior to the establishment of user accounts, please do not hesitate to contact us via email at cibmtr-centermaintenance@nmdp.org.

After the center is set up and user accounts are created, all questions and requests should be submitted via CIBMTR Center Support at https://nmdp.service-now.com/csm.

Also, see the New Center Information found on our website.