# CIBMTR Study Proposal Guide

This guide is intended to assist in the development of a successful CIBMTR study proposal. Because fewer than one third of proposals are selected, please review each of the following steps to determine if your study question is best answered through CIBMTR.

## 1. Establish Scientific Question(s) and Outcomes of Interest

- Select the most important primary outcome and 1-3 secondary outcomes for the study
    i. This will aid in selecting the most appropriate working committee and improve feasibility of the study

## 2. Choose a Working Committee

- Visit the Clinical Outcomes Research / Working Committees page of the CIBMTR.org website to determine which committee is most appropriate
    i. Review recent meeting materials to determine the committee that best suits the proposal based on disease, population, or topic

## 3. Determine if the Question has Previously Been Answered

- Complete a literature search to determine if CIBMTR or other organizations (e.g., EBMT) have asked similar questions recently
- Review meeting minutes from the past five CIBMTR meetings for the working group(s) that best fits the proposal and verify if similar proposals have already been accepted
    i. This will aid in determining the feasibility of the study (e.g., a study on haploidentical recipients may not have been possible due to low numbers several years ago, but with the increased incidence of haploidentical transplant, this question may now be feasible)
- Look through the list of recently published manuscripts by potential working groups

## 4. Verify if CIBMTR has the Necessary Data to Answer the Study Question

- Data Collection Forms
    i. CIBMTR collects data on donors and recipients with two general sets of forms, Transplant Essential Data (TED) forms and Comprehensive Report Forms (CRF)
        1. **TED forms** collect basic pre- and post-HCT data for federally required research such as analyses of center-specific outcomes and evaluation of optimal registry and cord blood bank size. Data from these forms may be best for a study that requires a large group of patients.
        2. **CRF forms** collect data included in research studies, though TED-level data may occasionally be used. These forms collect more detailed data including disease assessments at each follow up visit, expanded acute and chronic GVHD data, engraftment data, etc.

ii. View current and retired CIBMTR Data Collection Forms to determine if the needed data is or has previously been collected by CIBMTR

- Available (Prepared) Datasets
  i. If the study question is similar to a recently published CIBMTR project that was not previously answered, datasets are publicly available via the CIBMTR website
     1. The dataset can be analyzed using the study proposer's institutional statisticians which can be a simpler alternative to a formal proposal

## 5. Additional Data or Materials Beyond What CIBMTR has Already Collected

- Immunobiology Specimens
  i. CIBMTR collects several types of specimens and houses them in a tissue repository
     1. Biorepository Inventory Information
     2. To request specimens for studies that **do not** require clinical outcome data:
        a. Request biorepository inventory information: CIBMTR
        b. Request biorepository inventory information: BMT CTN
     3. Studies that require clinical data are processed through the Immunobiology Working Committee. In this case, it is strongly recommended that the co-chairs or scientific directors are contacted prior to proposal submission.
- Patient Reported Outcomes (PRO)
  i. CIBMTR collects patient reported outcomes on symptoms, functioning and other quality of life attributes (e.g., financial toxicity, return to work)
  ii. Additional information on what PRO measures have been collected and timepoints of collection can be found on the PRO Data Collection webpage
- Supplemental Data
  i. If retrospective data of interest is not presently available from CIBMTR, additional supplemental forms can be sent to individual centers to collect necessary data fields
     1. These proposals are considered on a case-by-case basis and typically require additional funding
     2. To gain a better understanding of feasibility, it is strongly recommended to contact the co-chairs or scientific directors of the relevant working committee(s) prior to submission

## 6. Contacting the Working Committee Chair(s) or Scientific Director

- After completing the above steps, if additional guidance is needed or there are questions (e.g., feasibility of the study, available data, past or present data collection forms) contact information for working committee members can be found on the individual working committee webpages