

**CENTER FOR INTERNATIONAL BLOOD AND MARROW
TRANSPLANT RESEARCH®**

**PROTOCOL FOR A RESEARCH DATABASE
FOR
HEMATOPOIETIC CELL TRANSPLANTATION,
OTHER CELLULAR THERAPIES AND MARROW
TOXIC INJURIES**

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July 2019
Version 8.1

ClinicalTrials.gov Identifier: NCT01166009

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1. Background

1.1 National Marrow Donor Program®

The National Marrow Donor Program® (NMDP) was established in 1986 as the result of a Federal contract that was awarded to create and maintain a registry of volunteer hematopoietic cell (HC) donors. Physicians search the NMDP Registry on behalf of patients in need of an HC transplant who have no suitably matching related donor. In 1999 the NMDP added a Cord Blood Registry to provide more donor source options for patients in need of an unrelated HC transplant. As part of the Federal contract the NMDP was required to collect outcomes data on patients who received a product through the NMDP.

In addition, the Federal contract also recognized that the NMDP could play a critical role in responding to contingency events; primarily radiation and chemical exposures occurring either accidentally or resulting from military or terrorist actions that cause a marrow toxic injury.

1.2 Medical College of Wisconsin

Since 1893, the Medical College of Wisconsin (MCW) has been a leader in patient care, research, education and community engagement. The International Bone Marrow Transplant Registry (IBMTR), of the Medical College of Wisconsin, was established in 1972 to monitor and study outcomes of bone marrow transplants. The IBMTR collected data submitted on a voluntary basis from U.S. and international transplant centers on recipients of allogeneic related and unrelated and autologous transplants.

1.3 Center for International Blood and Marrow Transplant Research®

In 2004, recognizing the significant overlap in their data collection efforts and research interests, NMDP and MCW established the Center for Blood and Marrow Transplant Research (CIBMTR) as a research collaboration between the two organizations. The CIBMTR has staff at both the NMDP and MCW.

The CIBMTR has a network of more than 400 centers worldwide that contribute detailed research data on consecutive allogeneic related and unrelated and autologous HC transplants. In addition, NMDP centers responsible for managing unrelated donors contribute detailed data on the donation and recovery of unrelated donors. In 2011 CIBMTR activities were expanded to include cellular therapies.

1.4 Establishment and Purpose of the Research Database

The original goal of the CIBMTR was to improve the safety and effectiveness of HC transplantation for both donors and recipients. That goal has since been expanded to include understanding the applications for cellular therapies and their associated patient outcomes, and to improve treatments and outcomes for those patients who have been exposed to radiation or other chemicals that are toxic to marrow.

The Research Database, which includes all transplant outcome data originally collected by NMDP and IBMTR, contains demographic and clinical data on patients and donors. The data in the Research Database are observational data. CIBMTR does not determine which therapies are used for patients, but rather collects information regarding therapies as they are applied by treatment centers.

The CIBMTR is the sole custodian of the data in the Research Database. The CIBMTR is responsible for determining to whom data in the Research Database may be provided (see Section 6 “Studies Involving Data in the Research Database”). The CIBMTR is responsible for determining if and when data will be removed from the database or shared with others.

The purpose of the Research Database is to have a comprehensive source of observational data that can be used by researchers to study HC transplantation and the application of cellular therapies, as well as a comprehensive source of observational data to study marrow toxic injuries. Listed below are examples of the types of studies in which data from the Research Database may be included.

Studies to determine:

- The success of various applications for transplantation and cellular therapies;
- How well recipients recover from their treatments;
- How short-term and long-term recovery after treatment can be improved;
- Molecular explanations for histocompatibility or clinical outcome revealed through analysis of genomic, epigenetic, or other biomolecular data;
- How access to treatment for different groups of patients can be improved, including studies designed to understand the financial or economic impact of treatments or studies designed to inform insurance/government payer policy, such as U.S. Medicare policy;
- How well donors recover from collection procedures;
- Success of different treatment models for marrow toxic injury, including HCT;
- The long-term effects of exposure to radiation or other chemicals;

2. Eligibility to Participate in the Research Database

2.1 Patient Eligibility Criteria

Any recipient of an unrelated or related allogeneic or autologous HC transplant or cellular therapy whose treatment takes place in a center participating in the

CIBMTR is eligible to enroll in the Research Database. This includes adults with and without decision making capacity and children.

2.2 Patients with Marrow Toxic Injury Eligibility Criteria

In the event of a radiation exposure accident, the NMDP has a radiation injury treatment network, whose purpose is to collect data to understand the outcomes of patients treated under these circumstances. Any patient who is treated for a marrow toxic injury at a center participating in the NMDP's Radiation Injury Treatment Network (RITN) is eligible to participate in the Research Database. This includes adults with and without decision making capacity and children. Eligible patients may have received supportive care only, growth factor support, HC transplant or other appropriate medical treatment for marrow toxic injury. Treatments applied are at the discretion of the care facility and are not determined by the NMDP or CIBMTR.

2.3 Unrelated Donor Eligibility Criteria

All donors registered on the NMDP Registry, regardless of whether they have been requested to donate a product for a patient, are eligible to participate in the Research Database.

2.4 Informed Consent

All U.S. enrollees will be provided information about participation in the Research Database and must sign an Institutional Review Board (IRB) approved informed consent document indicating their consent to participate in the database. Because the consent form is for participation in the Research Database, the consent form covers the first treatment as well as any subsequent treatments the patient has that are also included in the Research Database. Whenever possible, patients should be informed about the protocol and asked to provide consent to participate prior to their treatment. In the rare circumstance where that is not possible, it is acceptable to obtain the patient's consent after the treatment has occurred. The center where consent is obtained is responsible for maintaining the written consent form and documentation of the minor assent decision. To confirm that participants have given consent to participate in the Research Database, the first form submitted on a participant includes confirmation that the participant signed the informed consent document.

Institutional IRB policies must be followed regarding re-consent of minor patients when those patients reach the age of majority.

Non-U.S. centers contributing data to the Research Database will provide written assurance that the submission of data to the Research Database has on-going oversight by their local Ethics Review Board/Medical Ethics Committee and all regulations are followed.

2.4.1. Minor Assent

The Research Database includes pediatric patients. The procedural risk involved in this protocol meets the definition of minimal risk set forth in 45 CFR 46.102 (i) *“Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”* Participation on this protocol requires submission of medical data from recipients that are available directly from the patient’s healthcare record.

Adequate provisions must be made for soliciting and documenting assent of the children and permission of their parents or legal guardians, as set forth in 45 CFR 46.408.

- The research procedures do not involve more than minimal risk; therefore, assent will be sought from all minors 7 to 17 years of age capable of providing assent.
- Age appropriate information will be provided to minors 7 to 11 years of age and minors 12 to 17 years of age.
- Local Institutional Review Boards will be responsible for determining how assent will be documented.
- The research in this protocol is covered by 45 CFR 46.404; therefore, the written permission of the parent or legal guardian is required.
- The minor may only participate in the research if the minor and a parent or legal guardian agree to the minor’s participation. If either the parent/legal guardian or the minor declines participation in the study, the minor shall not be enrolled in the study. If the minor lacks the capacity to provide assent, parent or legal guardian permission is sufficient.

3. IRB Approval Process for Research Database

All U.S. centers must obtain IRB-approval for the protocol and consent forms prior to submitting participant data to the Research Database. The center may obtain IRB approval either through their local IRB or delegate review to the NMDP IRB through an IRB Authorization Agreement. The center’s designated IRB may not waive informed consent requirements under this protocol. Participants must provide informed consent for submission of their data to the Research Database.

This protocol and its associated consent forms are provided to centers on the CIBMTR website, www.cibmtr.org.

International centers must follow their own regulations and provide assurance to the CIBMTR that regulations are being followed.

3.1 IRB Approval Process

- The protocol and consent forms may be modified to include the name of the local institution, local institutional contact, and to conform to other similar non-substantive format or content changes required by the center’s designated IRB.
- The modified protocol and consent forms must be reviewed and approved by the center’s designated IRB.
- Any substantive changes to the protocol or consent forms suggested or stipulated by the local IRB must be reviewed and approved by the NMDP IRB.
- The IRB approval letter and the IRB-approved protocol and consent forms must be submitted to the NMDP IRB Office.
- Centers may begin submitting data as soon as the site’s Principal Investigator receives notification from NMDP IRB staff acknowledging that an IRB-approved protocol and consent form is in place at the center.
- The above process is followed for each continuing review period if the center has not transitioned the protocol to the 2018 Common Rule requirements. If the center transitioned the protocol to the 2018 Common Rule requirements, then the above process is only followed when there are amendments to the protocol or consent forms. If there is a lapse in IRB approval, the center will not be allowed to submit data for research purposes until IRB approval has been obtained.
- In cases where the center is relying on the NMDP IRB for this protocol the center does not need to obtain any additional IRB approval.

4. Collection of Data

4.1 Collection of HC Transplantation and Cellular Therapy Data

Patient data are collected from pre-existing data within the patient’s healthcare record chart at the treatment center. Treatment Centers submit data at the following time-points.

| Time-point | Data Collected |
|-----------------|---|
| At registration | Name Social Security Number (U.S. participants only) Mother’s maiden name City State Country of birth Race/ethnicity If patient/donor/legal guardian provides written consent to collect contact information, the following will also be collected: Address |

| | |
|---|--|
| | Phone numbers Email address |
| At the time of treatment | Demographic data Median household income (U.S. participants only), Education (U.S. participants only), occupation HLA typing data Treatment disease-specific data such as blood counts, disease status, cytogenetics Co-existing disease at the time of treatment Functional status Organ function prior to treatment History of infection exposure prior to treatment Conditioning regimen HSC or cellular therapy product manipulation |
| 100 day, six months, annually and biannually starting year six post-treatment | Engraftment – neutrophil and platelet recovery* Acute and chronic GVHD Chimerism Organ function Treatment toxicities New malignancy Disease Status Functional status Ability to return to work or school Second transplant Additional treatments Donor leukocyte infusion Pregnancy Quality of life indicators such as socioeconomic data *Not all data are collected at every time point |
| At time of death | Primary and contributing cause of death |

4.2 Collection of Marrow Toxic Injury Data

Data from patients with marrow toxic injury are collected from pre-existing data within the patient’s healthcare record at the treatment center. Treatment Centers submit data at the following time-points.

| Time-point | Data Collected |
|-----------------------------------|--|
| At registration | Name Social Security Number (U.S. participants only) Mother’s maiden name City State Country of birth |
| At the time of initial evaluation | Demographic data such as race and ethnicity, gender, birth date, |

| | |
|--------------------------|--|
| | Pre-existing medical problems Exposure history Patient trauma Organ function Blood counts and marrow status Treatment data and infection prophylaxis |
| At follow-up time points | Response to treatment including: Blood counts Laboratory and clinical data pertaining to organ injury New malignancy Functional status Additional treatments Infections Other complications following the marrow toxic injury |
| At time of death | Primary and contributing cause of death |

4.3 Collection of Unrelated Donor Data and Product Data

Unrelated donor data may be collected at the time a donor joins the Registry, when a donor is requested for confirmatory typing to determine if he/she is a match with a potential recipient, during the work-up phase to determine eligibility to donate HC, and post-collection of the HC product. Donor Center staff, and in some cases Treatment Center staff (i.e., confirmatory HLA typing data), submit data at the time-points listed below. All data submitted are abstracted from the donor's donation records maintained at the centers that are managing the donor's donation process and product collection. All data are collected as part of the standard donation process.

Additionally, the donor product may be tested to determine the number and types of cells, and to test for sterility and other factors important to the quality of the product. Data collected as part of the product analysis are included in the Research Database and may also be used for research purposes.

| Time-point | Data Collected |
|---|---|
| At the time the donor joins the Registry* | HLA typing Race Gender Date of birth |
| At the time a donor is requested for confirmatory typing* | HLA typing (submitted by transplant center) Infectious disease markers for hepatitis B and C, syphilis, HIV, CMV, HTLV I/II Weight ABO, Rh (D ^U) type Allogeneic blood transfusion Number of pregnancies |
| At the time of the donor | Pre-existing medical conditions |

| | |
|---|--|
| work-up for HC donation | Infectious disease markers for hepatitis B and C, syphilis, HIV, CMV, HTLV I/II ABO, Rh (D ^U) type Serum pregnancy test Screening for hemoglobin S (sickle hemoglobin) |
| During filgrastim injections (PBSC donors only) | Complete Blood Count Modified Toxicity Criteria |
| At the time of product collection* | Number and type of cells Sterility Other product factors related to transplant |
| Post HC collection Weekly until recovery One month, six month post collection Annually | Adverse events related to HC collection Ability to return to work, school, and leisure activities Complete Blood Count (at annual follow-up only) Modified Toxicity Criteria Health status |

* These data are collected by the NMDP as part of the search and donation process and will only be included in anonymous research studies or studies that are deemed non-human subject research by the criteria included in the October 2008 OHRP Guidance titled *Research Involving Coded Private Information or Biological Specimens*, unless the donor gives consent to participate in the Research Database at either the time he/she joins the Registry or is requested to donate for a patient. If consent is given, these data could be used in a linked research study.

4.4 Collection of Study Specific Data

In addition to the standard data collected at specified time points from patients and donors (see Section 4.1 “HC Transplantation and Cellular Therapy Data”, 4.2 “Marrow Toxic Injury Data” and Section 4.3 “Unrelated Donor Data”), additional participant data may be collected as needed for a specific study. In these cases, any of the required additional data would be data that are available in the participant’s healthcare record or donation record. Examples of additional data that may be requested for a specific study are more detailed clinical data at time of diagnosis or more detailed disease status data post-transplant.

In the rare event a participant would need to be contacted directly for additional data covered by this protocol, IRB approval would be required for the specific study as well as IRB-approved consent from the participant for the specific study.

4.5 Collection of Patient Reported Outcomes Data

Patient reported outcomes (PRO) data will be collected under a separate CIBMTR single institution protocol titled *Protocol for Collection of Patient Reported Outcomes Data*. Data collected under the *Protocol for collection of Patient Reported Outcomes* will be entered into the Research Database. Once PRO data

enter the Research Database, their maintenance, protection and access to by researchers are governed by this CIBMTR multi-institutional protocol, *Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries*

5. Collaboration with Other Registries

The CIBMTR establishes collaborative data sharing relationships with international and U.S. registries that are either therapy or disease registries. These data sharing relationships include:

1. Exchange of patient data where the patient exists only in one or the other registry but the patient data are of interest to both registries. For example, The European Group for Blood and Marrow Transplant (EBMT) transmits patient outcomes data to the Research Database for patients reported to EBMT but not to the CIBMTR, or
2. Exchange of patient data where the patients exist in both registries but the registries hold different types of data for the patient. For example, the exchange of patient data with the United States Immunodeficiency Network (USIDNET) for patients who are enrolled in both the USIDNET database protocol and the CIBMTR Research Database protocol.

In either scenario, data sharing may be on an on-going basis to include sharing of data as new patients are added to either registry, or on a discrete basis for a specific study. Agreements are established with the collaborating registries prior to the exchange of data and include conditions requiring that patients have given consent to research use of their data and to the sharing of their data with other registries or investigators.

If patient identifiers will be used to match patients in another registry with patients in the CIBMTR Research Database, administrative approval by the NMDP IRB Administrator or designated NMDP IRB staff is required.

6. Collaborations with Other Organizations

To advance all aspects of its research agenda, the CIBMTR may enter into data sharing agreements with other organizations that allow data to be shared on participants who reside in both the CIBMTR Research Database and the collaborating organization's database. Data sharing agreements include provisions to ensure that both the CIBMTR and the collaborating organization have obtained participant consent that allows sharing of data with other organizations as well as defining the use of the shared data and provisions to ensure that data privacy and security measures are in place to protect the data.

Each data sharing collaboration will be reviewed by the NMDP IRB Chair, or designee to determine if participant consent for the data exchange is covered by the

participant's consent to participate in the Research Database or if additional consent must be obtained from the participant. If additional consent is required a separate consent form will be created that will be under the umbrella of the Research Database protocol. Data sharing will not be initiated until the NMDP IRB has reviewed and approved the consent form and participant consent is obtained.

Examples of data sharing agreements include collaborations with healthcare performance organizations or collaborations with consumer-oriented third-parties such as personal health or family genealogy companies. Examples of data shared within these agreements may include, but are not limited to, diagnosis and procedure codes, utilization of services data, genetic or genomic data, socioeconomic data or clinical data. With appropriate consent in place, data may be exchanged on any participant in the Research Database. Studies initiated as a result of these data sharing agreements are included in the portfolio of research studies covered by this Research Database protocol and follow processes described in this protocol.

7. Studies Involving Data in the Research Database

7.1 Who May Request Access to Data

The data in the Research Database are available to researchers both within the CIBMTR network and outside the network. The CIBMTR defines the policies and procedures for release of data.

7.2 How Requests Are Reviewed/Approved

Any investigator may propose observational research studies to the CIBMTR. Research Database proposals are reviewed and approved by one of the CIBMTR's scientific committees, CIBMTR scientific leadership, to ensure that the study is scientifically sound. Each study is also reviewed by the CIBMTR Observational Research group to ensure that the study is within the limits defined in the Research Database protocol and is covered by the participant's informed consent document. Studies that fall outside the limits defined in the Research Database protocol will be reviewed by the NMDP IRB. In these cases, additional consent may be required from the participant.

The CIBMTR Observational Research group maintains a complete list of studies that fall under the Research Database protocol and submits the list annually to the NMDP IRB. If studies are added throughout the year, updates are sent to the NMDP IRB. This list is for reference only; it does not require action by the NMDP IRB.

7.3 How Data Sets are Prepared and Shared

A data extract plan is prepared and the data necessary to conduct the study are extracted from the Research Database into a study-specific research dataset. In most cases the data analysis for a study is conducted by CIBMTR research staff. Data extracts that are prepared for analysis by CIBMTR staff never include

individually identifiable data beyond treatment center, birthdate and treatment, relapse and death dates. Data from these analyses are shared with investigators, but always as summarized, aggregate data.

On the rare occasion where analysis will occur at an individual investigator's institution, no identifying information is released beyond a randomly generated ID number (distinct from the CIBMTR ID numbers) where CIBMTR maintains the code for the random ID number. At no time is an individual investigator given the names of participants, or the identity of the center where the participant was treated. All relevant dates pertaining to a study are replaced with calculated time interval values.

7.4 Studies Designed to Inform U.S. Medicare Policy

The United States Centers for Medicare & Medicaid Services (CMS) provides expanded payment coverage for some HC transplantation and cellular therapy indications under Coverage with Evidence Development (CED). To qualify for coverage, transplants and cellular therapies for these indications must take place within a CMS-approved clinical study that meets federal guidelines. CIBMTR develops prospective observational clinical studies for HC transplantation and cellular indications under CED and submits to CMS for approval. These prospective observational studies rely only on data collected under the Research Database protocol. Patients enrolled on CIBMTR studies for indications under CED will sign a separate consent form under the Research Database protocol for participation in a CMS CED-approved study. These patients will be invited to participate in both the CMS CED study and the Research Database protocol. Patient participation in the CMS CED study is not dependent on their participation in the Research Database protocol.

8. Participant Withdrawal from the Research Database

At any time, a participant may request that his or her data no longer be made available for research purposes. The participant may make this request either directly to the NMDP or CIBMTR or through his or her corresponding center. Data for participants that withdraw from the database will not be available for future research studies but will be retained in the database for non-research purposes, such as required government reports. Data that has already been included in research studies cannot be removed from those research datasets.

9. Patient Contact Information

As part of the consent process to participate in the Research Database protocol, transplant and cellular therapy patients will also be asked if they are willing to provide their contact information and preferred language to the CIBMTR. The sole purpose for collecting the patient contact information is for CIBMTR staff to invite transplant or cellular therapy patients to join studies that require direct contact with the patient, including patient-reported outcomes studies. Patient-reported outcomes studies will be conducted under the protocol, *Research Database Protocol for*

Patient Reported Outcomes. Studies that include direct contact with the patient but are not patient-reported outcomes studies, will be conducted under separate study-specific protocols. The *Research Database Protocol for Patient Reported Outcomes* and other direct patient contact studies require NMDP IRB approval and patient consent to the specific study. Patient contact information will be stored in the same manner as other identifying participant information as described in Section 10 “Data Confidentiality.”

10. Data Confidentiality

Access to all information in the Research Database is tightly controlled with passwords and logins at multiple levels. Access to the Research Database is limited to those employees who have specific job responsibilities related to the database.

All paper forms containing participant information are filed in a locked area. Only those employees who have specific job responsibilities related to the files have access to the files.

Donors are assigned a donor identification (DID) number and a Global Registry Identifier for Donors (GRID) when they join the NMDP Registry. The DID/GRID contains no identifying information. This DID/GRID is used to track all donor information in the Research Database.

Patients are assigned a unique identification number when the treatment center registers them with the Research Database. Patient first and last name, social security number (U.S. patients only), mother’s maiden name, and city, state and country are collected at the time the unique identification number is assigned to ensure that the patient has not been previously registered by another center. On a subset of patients that agree to be contacted directly by CIBMTR for future studies, address, phone number and email address will also be collected (see Section 9 “Patient Contact Information”). These identifying data are stored in a secure table that can only be accessed by two authorized s. These identifying data are never included in data sets for analysis. The unique identification number contains no identifying information within it. This number is used to track all information about the patient in the Research Database.

The identity of participants in the Research Database is kept confidential at all times. Identifying information that is kept in the Research Database for patients includes transplant or cellular therapy date, birthdate, and location of treatment. Identifying information that is kept in the Research Database for patients with marrow toxic injury includes, exposure date, birthdate, location of treatment. Identifying information that is kept in the research database for donors is birthdate, donor center, and date and location of HC collection. Data released to investigators outside the CIBMTR does not include identifying data (See Section 7.3 “How Data Sets are Prepared”).

The Research Database protocol is covered by a National Institutes of Health Certificate of Confidentiality (CoC) The CoC protects identifiable research

information from forced disclosure in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

All research staffs at the CIBMTR and the NMDP maintain up-to-date training in protection of human subjects. This training is received through the Collaborative IRB Training Initiative (CITI) program. This is a web-based training program offered through the Biomedical Research Alliance of New York (BRANY).

Additionally, NMDP and MCW maintain appropriate technical and organizational measures for the adequate protection of the security and privacy of its systems and data. These protections comply with the United States National Institute of Standards and Technology, Security Controls for Federal Information Systems (NIST 800-53), and all other applicable security and data privacy requirements. These safeguards are audited annually by a qualified independent auditor; results are reported to CIBMTR management for timely resolution.