Center for International Blood and Marrow Transplant Research®

PROTOCOL FOR A RESEARCH SAMPLE REPOSITORY

FOR

HEMATOPOIETIC CELL TRANSPLANTATION, OTHER CELLULAR THERAPIES AND MARROW TOXIC INJURIES

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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/Be The Match® Registry on behalf of patients in need of an HC transplant who have no suitably matching related donor. As part of the Federal contract the NMDP was required to collect outcomes data and research samples on patients who received a product through NMDP. In 1999 the NMDP added a Cord Blood Registry to provide more donor source options for patients in need of an unrelated HC transplant or cellular therapy. In 2006, the NMDP was awarded a subcontract by the Medical College of Wisconsin to serve as the Related Transplant Research Repository for the Stem Cell Therapeutic Outcomes Database (SCTOD). The Medical College of Wisconsin – Center for International Blood and Marrow Transplant Research (CIBMTR) holds the federal contract to operate the SCTOD.

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 Center for International Blood and Marrow Transplant Research®

The International Bone Marrow Transplant Registry (IBMTR), located with the Department of Medicine of the Medical College of Wisconsin, was established in 1972 to monitor and study outcomes of bone marrow transplants. In 2004 the NMDP

and IBMTR established the Center for Blood and Marrow Transplant Research (CIBMTR). The CIBMTR is a research affiliation between the NMDP and the Medical College of Wisconsin. The CIBMTR has both a Minneapolis campus located within the NMDP offices and a Milwaukee campus at the Medical College of Wisconsin. The NDMP Research Program is accomplished through the CIBMTR.

1.3 Establishment and Purpose of the Research Sample Repository

In 1987 the NMDP established the Research Sample Repository which is currently located at the NMDP Biorepository Services facility in New Brighton, Minnesota with a backup location at the Coriell Institute for Medical Research in Camden, New Jersey. The primary objective of this repository is to make blood samples available for research studies related to histocompatibility and HC transplantation or other cellular therapy. Blood samples are donated by donors, CBUs and recipients who have registered, donated or received a HC transplant or other cellular therapy covered under the C. W. Bill Young Transplantation Program. Details of the research sample inventory are available at http://www.cibmtr.org/Samples/Inventory/Pages/index.aspx.

The Research Sample Repository maintains updated standard operating procedures (SOP) for all aspects of operation including but not limited to: sample receipt, sample handling, sample culture, sample labeling, sample storage and sample retrieval and shipment.

The following are types of studies that the samples may be used for without obtaining additional consent from the recipient. Studies to:

- Investigate molecular explanations for histocompatibility or clinical outcome revealed through analysis of genomic, epigenetic, or other biomolecular data;
- Determine and evaluate the factors that affect transplant or cellular therapy outcome;
- Study the distribution of HLA tissue types in different populations; e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types.
- Studies of the success of transplantation, cellular therapies or supportive care in the management of marrow toxic injuries.
- Use for delinked (anonymous) research.

2. Eligibility to Participate in the Research Sample Repository

2.1 Hematopoietic Cell or Other Cellular Therapy Donors Eligibility Criteria

Donors are eligible to participate in the Research Sample Repository if they have donated or are scheduled to donate HCs or cellular therapy products to an allogeneic recipient either by a marrow harvest or by apheresis. This includes adults with and without decision making capacity and children.

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 Sample Repository.

2.2 Cord Blood Units Eligibility Criteria

Testable material from CBUs (Specimens) infused at treatment centers covered under the C. W. Bill Young Transplantation Program are eligible for inclusion in the Research Sample Repository. Material may be submitted by participating treatment centers, centralized laboratories and CBBs.

2.3 Hematopoietic Cell Transplantation or Other Cellular Therapy Recipients Eligibility Criteria

All ~~U.S.~~ recipients of allogeneic or autologous HC transplants or cellular therapies are eligible to participate in the Research Sample Repository. This includes adults with and without decision making capacity and children.

2.4 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 Sample Repository. This includes adults with and without decision-making capacity and children. Eligible patients may have received support care only, growth factor support, HSC 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.

2.5 Informed Consent to Participate in the NMDP Research Sample Repository

All participants, with the exception of CBU specimens, will be provided information about participation in the Research Repository and must sign an Institutional Review Board (IRB) approved informed consent document indicating their consent to participate in the repository. 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 Sample Repository, the first form submitted to the Research Database 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 samples to the Research Sample Repository will provide written assurance that the submission of samples has on-going oversight by their local Ethics Review Board/Medical Ethics Committee and all regulations are followed.

2.5.1 –Minor Assent

The Research Sample Repository includes pediatric patients and related donors. 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 a routine blood draw.

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 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.

2.5.2 Cord Blood Specimens

- Specimens obtained from a CBU used for transplant or cellular therapy do not involve human subjects according to the Office for Human Research Protections guidance released August 10, 2004 entitled, "Guidance on Research Involving Coded Private Information or Biological Specimens" by virtue of meeting the following criteria:
    - The specimens were not collected specifically for inclusion in the Research Sample Repository and related research activities, but rather for use in transplantation or cellular therapy.
    - The NMDP, treatment centers and centralized laboratories cannot readily ascertain the identity of the specimen donors because the coded identifying information key is held by the CBB and will not be shared with the NMDP

3. IRB Approval Process for Research Sample Repository

All treatment centers and donor centers must obtain IRB-approval for the protocol and consent forms prior to submitting patient and donor blood samples to the Research Repository. The center may obtain IRB approval either through their local

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IRB or delegate review to the NMDP IRB through and IRB Authorization Agreement. The center's designated IRB may not waive informed consent requirements under this protocol. Patients and donors must provide informed consent for submission of blood samples to the Research Repository.

This protocol and its associated consent forms are provided to centers on the CIBMTR website, www.cibmtr.org.
International centers must follow their own national regulations and provide assurance to the CIBTMR that national 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 template 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 blood samples as soon as the site's Principal Investigator 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 blood samples to the NMDP 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 Samples

4.1 Pre-Transplant or Cellular Therapy Collection of Donor and Patient Blood and Tissue Samples

Blood samples should be collected as indicated on the Research Repository Critical Facts Sheet and/or study specific consents.

4.1.1 Unrelated and Related Donor Transplants or Cellular Therapies

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Patient pre-transplant or cellular therapy samples are collected prior to the patient starting the preparative regimen for the transplant or cellular therapy. Up to ~~thirty~~ fifty milliliters (~~30~~ 50 mL) of blood can be~~are~~ collected from adult patients. For pediatric patients where the collection of the full sample is medically contraindicated, adjusted volumes will be outlined in study specific documents. ~~as little as one milliliter (1 mL) of blood may be collected.~~ Previously collected blood or tissue diagnostic samples may be requested for evaluation of primary disease for specific studies. Sample collection specifications will be outlined in ~~each consent specific to the research study.~~study specific documents.

~~Unrelated d~~Donor samples are collected either prior to the HSC or cellular therapy collection or after the collection, whichever is the most convenient and safe for the donor. Up to ~~thirty~~fifty- milliliters (~~30~~ 50 mL) of blood can be~~are~~ collected from adult donors.

In cases where donor or patient blood samples are not available, samples may consist of any material that could potentially yield testable DNA. Types may include red cell pellets, extracted DNA, dried blood on filter paper, viable cells, and any other testable material.

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4.1.2 Autologous Transplants or Cellular Therapies

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Patient pre-transplant or cellular therapy samples are collected prior to the patient starting the preparative regimen for the transplant or cellular therapy. Up to ~~thirty~~ fifty milliliters (~~30~~ 50 mL) of blood can be~~are~~ collected from adult patients. For pediatric patients where the collection of the full sample is medically contraindicated, adjusted volumes will be outlined in study specific documents.~~as little as one milliliter (1 mL) of blood may be collected.~~

4.2 ~~Post-transplant or~~ Cellular Therapy Collection of Patient Blood ~~and Tissue~~ Samples

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Post-transplant or cellular therapy samples may be requested on an event and/or calendar driven basis for allogeneic and autologous patients for specific research studies that fall within the objectives of this protocol. Events may include diagnosis of a secondary primary malignancy, disease relapse, diagnosis of acute or chronic graft versus host disease or other clinically relevant event. Up to fifty~~thirty~~ milliliters (5~~3~~0 mL) of blood can be ~~are~~ collected from adult patients. For pediatric patients where the collection of the full sample is medically contraindicated, adjusted volumes will be outlined in study specific documents.~~as little as one milliliter (1 mL) of blood may be collected.~~ Previously collected tissue samples may be requested for events including ~~diagnosis of primary disease and or~~ a secondary primary malignancy as well as other events listed above.

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Patient participation in the event or calendar driven sample collection is not dependent on prior participation in the Research Sample Protocol. In each case,

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consent specific to the research study will be obtained from the patient at the time of the event driven or calendar driven sample collection. Sample collection specifications will be outlined in study specific documents. These study~~project~~ specific consent forms will fall under the umbrella of this protocol. Sample collection will not be initiated until the NMDP IRB has approved the consent form and patient consent has been obtained.

4.3. Patients With Marrow Toxic Injury

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Samples are collected prior to the patient starting a preparative regimen if a transplant or cellular therapy is directed. Otherwise, samples are collected whenever convenient and safe for the patient. Up to fifty~~thirty~~ milliliters (50 mL) of blood can be~~are~~ collected from an adult. For pediatric patients, where the collection of the full sample is medically contraindicated, adjusted volumes will be outlined in study specific documents.~~as little as one milliliter (1 mL) of blood may be collected.~~

In cases where blood samples are not available, samples may consist of any material that could potentially yield testable DNA. Types may include red cell pellets, extracted DNA, dried blood on filter paper, viable cells, and any other testable material.

4.4 Donors for Tissue Type Characterization and Algorithm Enhancement

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Samples from registered volunteer donors with rare tissue types are collected after registration at a time convenient and safe for the donor. Up to fifty milliliters (50 mL) of blood are collected from an adult.

In cases where blood samples are not available, samples may consist of any material that could potentially yield testable DNA. Types may include red cell pellets, extracted DNA dried blood on filter paper, viable cells, and any other testable material.

4.5 Collection of CBU Specimens

CBU specimens may consist of any material remaining at the Cord Blood Bank, treatment center, or NMDP Confirmatory Typing Laboratory that could potentially yield testable DNA. Specimen types include red cell pellets, extracted DNA, dried blood on filter paper, viable cells, and any other testable material.

5. Sample Processing

5.1 Cell Storage

Donor and patient samples are stored as whole blood, peripheral blood mononuclear cells, cell lysates, extracted DNA, stabilized RNA, serum and plasma. These samples are stored in liquid nitrogen and/or –80°C freezer or as dried blood on filter paper. These samples are processed and stored according to standard operating procedures. Cord blood specimens are received and stored frozen.

5.2 Cell Transformation

An attempt is made to generate an Epstein-Barr Virus (EBV)- transformed B-Lymphoblastoid Cell Line (B-LCL) on donor and patient samples as needed to replenish inventory. B-LCLs provide a renewable source of DNA. Cell lines are developed according to standard operating procedures. No attempts are made to transform cord blood material because of the limited volume and absence of an effective procedure.

5.3 Cell Expansion

Transformed cells may be expanded in culture to replenish depleted inventory stores.

5.4 Vial Labeling

Samples are labeled with an identification number that includes no identifying information assigned to the donor, patient or CBU, and the date the sample was prepared and frozen.

6. Duration of Sample Storage at the Research Repository

Research samples will be stored at the repository until the material has been exhausted or the repository is discontinued. The NMDP/CIBMTR is the custodian of all samples in the Research Repository and may at its discretion destroy samples that it determines should not be retained. NMDP may transition responsibility to another custodian that meets all necessary requirements. If the repository is permanently closed all stored sample material will be destroyed.

Samples may be maintained beyond the death of the participant. In this case, samples will only be used for the histocompatibility related studies or completely anonymous research studies outlined in the "Use of Research Repository Samples" section below.

7. Access to Samples

7.1 Who May Request Access to Samples

Representatives of participating centers and investigators or research groups may request access to research samples contained in the Research Sample Repository for the purpose of conducting research. Medical Directors and Coordinators from the NMDP network may request and be provided samples collected by their own centers, provided there are sufficient aliquots in the Repository to do so.

7.2 How Requests Are Reviewed/Approved

Samples are released according to policies established and maintained by the NMDP/CIBMTR. Briefly, requests are reviewed by NMDP/CIBMTR staff who determine if committee approval is needed to release the sample(s). Participating centers requesting samples from subjects from their own center for the specific purpose of treating a donor or a patient do not need committee approval to access the samples. Requests for samples for use in a research study that includes correlation

with clinical outcome data must be reviewed and approved for scientific merit by a CIBMTR Working Committee. Following CIBMTR committee approval, the Repository Oversight Committee must approve the release of the samples for the study. If the study is scientifically sound, the Research Repository Principal Investigator performs an administrative review of the study protocol to ensure that it is within the limits defined in the Research Repository protocol and is covered by the participant's informed consent document for the Research Repository. Requests for samples for use as reference or quality control material must be reviewed and approved by the Repository Oversight Committee and the Research Repository Principal Investigator prior to release of the samples.

In summary, all sample requests must meet the following release criteria prior to distribution of samples:

- The proposed use of samples falls under the acceptable uses defined under section 8.1 for linked research or 8.2 for anonymous research per Research Repository Principal Investigator.
- The proposed study is deemed scientifically sound, feasible and high impact through acceptance by a CIBMTR Working Committee or
- The planned use is for reference or quality control material only.
- The proposed study is approved by the Repository Oversight Committee.
- Consent status is confirmed in the CIBMTR database.

8. Use of Research Repository Samples for Research Studies

The Research Repository Principal Investigator will administratively review each study proposal after it has been approved for scientific merit. If the Research Repository Principal Investigator determines that the study proposal falls within one of the listed categories of research, then consent beyond the initial consent obtained from the Repository participant is not necessary nor is full committee review.

8.1 Linked Research

Linked research is any research where a mechanism exists to trace data or samples back to the identity of the research subject. This includes, but is not limited to, any of the following research that investigates factors influencing the outcomes of unrelated and related donor HCT and cellular therapies:

- Studies of histocompatibility including HLA typing, analysis of allele and haplotype frequencies in different populations, evaluation of microsatellites and single nucleotide polymorphisms, examination of minor ~~histocompatibility~~histocompatibility antigens, or other factors known or found to be involved in donor / recipient histocompatibility.
- Studies of immune regulatory systems including interleukins, interferons, tumor necrosis factors and others as these may influence the outcomes of transplantation or cellular therapy.
- Studies of molecules involved in natural defense systems such myeloperoxidases, oxidative enzymes, perforins, defensins, adhesion molecules and others.

- Studies of other molecules that may influence the outcomes of transplantation or cellular therapies including coagulation factors and coagulation regulators, platelet and endothelial cell functional and regulatory systems, complement systems, and others.
- Studies of molecular systems known or found to be involved in the proliferation or maintenance of hematopoietic and immune systems including growth factors, cell surface and cytoplasmic receptors, cell cycle regulators, DNA and gene regulatory molecules, DNA telomeres, and others.
- Studies of global genetic diversity through genome-wide association studies or other techniques to evaluate the impact of other genetic factors on transplant or cellular therapy outcome.
- Studies of the success of transplantation, cellular therapies or supportive care in the management of marrow toxic injuries.

8.2 Delinked (Anonymous) Research

Delinked (anonymous) research is research where it is impossible under any circumstances to trace data or samples back to the identity of the research subject. Any research project may be proposed for anonymous research, examples include:

- Studies that require self-identified race/ethnicity or other demographically defined healthy and/or disease controls.
- Studies that need HLA specific immune stimulators for in vitro assays.

Such projects follow the process for review and approval as outlined in Section 7.2.

- Samples provided for anonymous research will have identifiers removed and replaced with appropriately designed, non-traceable serial numbers.
- Subject to the "Data Available with Samples" section below, samples may be combined with outcome data from NMDP/CIBMTR databases prior to anonymization. In such instances, all personal identifying information including names, ID numbers, birthdates, addresses, admission dates, hospitalization sites, etc. will be removed. Personal identifiers deemed necessary for the research, e.g., zip codes, will only be provided following Research Repository Principal Investigator.

8.3 Studies Outside the Scope of this Protocol

In cases where an investigator proposes research that does not fall under the guidelines set forth in the "Use of Research Repository Samples" section above, the proposal will be reviewed for scientific merit according to NMDP/CIBMTR policies. If approved based on the scientific merit, the study will be subject to IRB review and approval, including a determination of the requirements for additional informed consent, if any.

8.4 Data Available With Samples

Research studies using Research Repository samples may include data from the NMDP/CIBMTR Research Database, subject to provisions of the Research Database protocol and NMDP policies and procedures.

8.5 Restrictions on Sample Usage at the Investigative Site

- The intended use for the Research Repository samples is to facilitate research projects.
- Commercial use of samples from the Research Sample Repository is strictly forbidden without the prior written consent of the NMDP.
- Third-party distribution of any of the samples from the Research Sample Repository is strictly forbidden without the prior written consent of the NMDP.
- Upon request, the requestor shall return to the NMDP any samples obtained from the Research Sample Repository.
- After testing is complete, samples must be disposed of according to local and state biohazardous waste laws.
- Samples must not be retained indefinitely.
- Requestor will not receive any identifying information with the samples that could possibly be used to link the sample to the contributing individual.

8.6 Public Release of Data Generated on Samples

Research studies using Research Repository samples funded through the National Institutes of Health (NIH) are subject to the public data release policies of the NIH. The deposition of testing data from Research Repository samples into the NIH database of Genotypes and Phenotypes (dbGAP) will be permitted under the following conditions:

- Access to sample data through dbGAP is limited to the controlled-access data process and use limited to research purposes defined in the consent.

9. Participant Withdrawal from the Research Sample Repository

At any time, a participant may request that his or her sample be removed from the Research Sample Repository. The participant may make this request either directly to the NMDP/CIBMTR or through his or her corresponding treatment or donor center. Any unused sample will be destroyed.

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10. Confidentiality

10.1 Coded Sample Inventory, Links to Personal Identifiers and Staff Training and Access

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All records pertaining to the identity of participants in the NMDP Research Repository will be kept private and confidential. Personal identifying information will only be released with the express written permission of the participant.

Blood samples and all records associated with blood samples will be labeled only with an alphanumeric code that contains no personal identifiers. A link does exist between the participant's name and the alphanumeric code. This link is not available to staff at the NMDP Research Sample Repository. The link will never be released to an investigator.

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

All research staff 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.

10.2 Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the Federal Government. The research team will not disclose or use information, documents, or biospecimens that may identify participants in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless the participant consented for this use. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project if that information is needed for auditing or program evaluation.

10.3 Reporting Requirements for Research Sample Requests

Progress reports on the status of research using samples obtained from the Research Sample Repository must be submitted as required by the NMDP/CIBMTR.