# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

**Current Protocol Version 9.1 (PI Change) June, 27, 2022**
Version 9.0 (Amendment) September 30, 2021
Version 8.1 (Amendment/Annual Report) July 9, 2020
Version 8.1 (Amendment/Annual Report) July 30, 2019
Version 8.0 (Continuing Review) – July 30, 2018
Version 7.5 (Continuing Review) – July 30, 2017
Version 7.5 (Amendment) – February 8, 2017
Version 7.4 (Continuing Review) –July 30, 2016
Version 7.3 (Continuing Review) – July 30, 2015
Version 7.2 (Continuing Review) – July 30, 2014
Version 7.1 (Continuing Review) –July 30, 2013
Version 7.1 (Amendment) – September 6, 2012
Version 7.0 (Continuing Review) – July 30, 2012
Version 6.0 (Continuing Review) – July 30, 2011
Version 6.0 (Continuing Review) – July 30, 2010
Version 5.0 (Continuing Review) – July 30, 2009
Version 4.1 (Continuing Review) – July 30, 2008
Version 4.1 (Continuing Review) – July 30, 2007
Version 4.0 (Amendment) – April 26, 2007 (Effective 6/11/07)
Version 3.0 (Continuing Review) – July 30, 2006
Version 2.2 (Continuing Review) – July 30, 2005
Version 2.1 (Continuing Review) – July 30, 2004
Version 2.0 (Continuing Review) – October 1, 2003
Version 1.0 – July 2002

| Description of Revision | Document/Section(s) Affected | Effective Date |
|---|---|---|
| Title Page:<br>Removed Dr. Douglas Rizzo as Principal Investigator<br><br>Added: Dr. Patricia Steinert, PhD as Principal Investigator | Protocol Title Page | 6/27/2022 |
| Section 7:<br>Removed Dr. Doug Rizzo and contact information.<br>Corrected grammar by removing term “either” from recipient consents.<br><br>Footer:<br>Updated revision and version numbers<br>Updated Copyright year to “2022”<br>Updated document titles for quality control | Adult Autologous Recipient<br>Adult Allogeneic Recipient<br>Adult CMS<br>Marrow Toxic Injury<br>Unrelated Donor Consent Forms | 6/27/2022 |
| Section 2:<br>Added: “If you join the Research Database” to the beginning of Section 2. | Adult Marrow Toxic Injury<br>Consent Form | 12/6/2021 |
| Removed Donor ID from footer. | Adult Donor Consent Form | 12/6/2021 |
| Section 2:<br>Added: “Regardless of whether you join the Research Database, your doctor will send data about your disease and your transplant or cellular therapy to the CIBMTR.<br><br>Added additional language to clarify that if the participant joins the study, their data will be used in research. | Adult Allogeneic Recipient<br>Consent Form | 12/6/2021 |
| Section 2:<br>Added statement about information being collected regardless of whether participant joins the research database. | Adult Autologous Recipient<br>Consent Form | 12/6/2021 |

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| Added additional language to clarify what happens if the participant joins the study. | | |
| Section 1:<br>Added statement about being able to partake in the CMS study without participating in the Research Database.<br><br>Removed Statement: "your healthcare costs are covered by Medicare"<br>Added: "you have healthcare insurance coverage from Medicare"<br><br>Removed: "The goal of this research is to see how well BMT works to treat your disease"<br><br>Section 2:<br>Clarified that data may be used in future research studies related to Medicare coverage of participants disease.<br><br>Section 3: Added language to clarify coverage subject to copays, deductibles, and other fees.<br><br>Section 4:<br>Removed: NCT Identifier Number<br><br>Added: "Centers for Medicare and Medicaid Services (CMS)" to the list of groups that may access participant's medical records<br><br>Removed statement about CIBMTR selling data to third parties from CMS consent; | Adult CMS Studies Consent Form | 12/6/2021 |
| Section 5:<br>Added language to Reimbursement and Cost section of CMS Consent about Medicare covering the cost of transplant and that patient may be responsible for other costs like copays and deductibles. | Adult CMS Studies Consent Form | 12/6/2021 |
| Section 5:<br>Removed "A drug company may develop a new product or therapy for patients using information from the Research Database. If this happens, you will not be paid". | Adult Donor Consent Form<br>Adult Allogenic Recipient<br>Adult Autologous Recipient;<br>Adult Marrow Toxic Injury;<br>Adult CMS Studies | 12/6/2021 |
| Minor grammatical and formatting updates throughout consent forms to eliminate redundancies and improve clarity. | Adult Donor Consent Form<br>Adult Allogenic Recipient<br>Adult Autologous Recipient;<br>Adult Marrow Toxic Injury;<br>Adult CMS Studies | 12/6/2021 |
| Signature page updated to include new format for capturing interpreter signature and witness signature if applicable. | Adult Donor Consent Form<br>Adult Allogenic Recipient<br>Adult Autologous Recipient;<br>Adult Marrow Toxic Injury;<br>Adult CMS Studies | 12/6/2021 |
| Section 10: Added clarifying language on how CIBMTR | Protocol: Section 10 | 12/6/2021 |

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| securely stores and handles patient data. | | |
| Section 9: Edited language to better describe the collection and use of Patient Contact Information. | Protocol: Section 9 | 12/6/2021 |
| Section 4.3:<br>Replaced "filgrastim injections" with broader "mobilization agent administration".<br><br>Removed Annual timepoint from Post HC collection schedule. | Protocol: Section 4.3 | 12/6/2021 |
| Section 4: Added administrative claims data as a source of data collection and added language to clarify that the exact data being collected may evolve with changes in standard practice. | Protocol Section: 4 | 12/6/2021 |
| Section 1.4: Added language to identify data collected under the protocol may be used in combination with specimens collected by the CIBMTR protocol for Research Sample Repository | Protocol Section: 1.4 | 12/6/2021 |
| Section 1: Renumbered and reformatted subsections 1.1 through 1.4 for numerical flow. | Protocol: Section 1 | 12/6/2021 |
| Updated language to reduce language level and increase subject understanding | All consent forms | 07/09/2020 |
| Section 4: Confidentiality and Use of Information language expanded | Adult Donor Consent Form<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Adult Marrow Toxic Injury;<br>Adult CMS Studies | 07/09/2020 |
| Section 5: Cost and Reimbursement language expanded | Adult Donor Consent Form<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Adult Marrow Toxic Injury;<br>Adult CMS Studies | 07/09/2020 |
| 1. Overall edited to reduce redundancies and create better flow of information in the protocol.<br>2. Removed references to data being collected on forms as data may be collected by other modes.<br>3. Substituted the generic "patient" to describe all individuals who received a HC transplant, cellular therapy or treatment for marrow toxic injury.<br>4. "Recipient" was only used when "patient" would not make sense in the context of the sentence.<br>5. Substituted the "participant" for "patient and donor" when referring to both.<br>6. Substituted "treatment center" for "transplant center."<br>7. Substituted "healthcare record" for "medical record."<br>8. Deleted all references to regenerative medicine and used the more generic "cellular therapy." | Protocol: throughout the entire protocol. | 07/30/2019 |
| Broke Section 1.2 into two distinct sections – 1.2 for Medical College of Wisconsin and 1.3 for CIBMTR | Protocol: Section 1 | 07/30/2019 |

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| Added a statement to clarify that participants only need to sign one consent form even if they are receiving multiple subsequent treatment that covered under this protocol. | Protocol: Section 2.4 | 07/30/2019 |
| Added that centers can delegate review of the protocol to the NMDP IRB through an IRB Authorization Agreement. Added that protocol and consent forms can be found on the CIBMTR website. | Protocol: Section 3 | 07/30/2019 |
| Updated to include process for 2018 Common Rule Requirements. | Protocol: Section 3.1 | 07/30/2019 |
| Added product data collection. | Protocol: Section 4.3 | 07/30/2019 |
| Added section on patient reported outcomes. | Protocol: Section 4.5 | 07/30/2019 |
| Administrative IRB approval for using patient identifiers when linking data with external collaborators was switched from the IRB chair to IRB administrator. This section was also rewritten at a higher level with examples provided, whereas the previous version listed all instances of collaboration with other registries. | Protocol: Section 5 | 07/30/2019 |
| Last paragraph of section rewritten at a higher level with examples of types of collaboration and types of data that may be exchanged. | Protocol: Section 6 | 07/30/2019 |
| Section 7.2 was broken into two distinct sections – 7.2 How Requests are Reviewed/Approved and 7.3 for How Data Sets are Prepared and Shared | Protocol: Section 7.2 and 7.3 | 07/30/2019 |
| Responsibility for ensuring that research studies using data from Research Database fall within the scope of the protocol and consent from was switched from an administrative review by the IRB chair to the CIBMTR Observational Research group. | Protocol: Section 7.2 | 07/30/2019 |
| Statement was added about what happens to a patient's data when he/she withdraws from the protocol. | Protocol: Section 8 | 07/30/2019 |
| The patient's preferred language was added to the contact information that is collected if a patient agrees to provide contact information to the CIBMTR. | Protocol: Section 9 | 07/30/2019 |
| Statement was added that studies that require direct contact with the patient by CIBMTR will be conducted under the CIBMTR protocol *Research Database Protocol for Patient Reported Outcomes.* | Protocol: Section 9 | 07/30/2019 |
| Added that donors will also be assigned a Global Registry Identifier for Donors (GRID) when they join the NMDP Registry. The GRID will be used to track donor information in the Research Database. | Protocol: Section 10 | 07/30/2019 |
| Changed title of consent form: Adult <u>Unrelated</u> Donor Research Consent Form | Unrelated Donor Consent Form: | 07/30/2019 |
| Section 2, beginning of second paragraph added:<br><u>Your donation-related data may be shared with researchers, collaborating organizations, or other registries outside the CIBMTR. The data that is shared will not include any information that could identify you.</u> | Unrelated Donor Consent Form: | 07/30/2019 |
| Section 3, second to last sentence in paragraph added:<br><u>You will not directly receive any results generated from this research.</u> | Unrelated Donor Consent Form: | 07/30/2019 |

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| Section 5 added the sentence:<br>Your data may be used for commercial projects and profit. If your data is used for commercial projects, you will not share in any profit. | Unrelated Donor Consent Form: | 07/30/2019 |
| Just under the title:<br>~~*Informed consent to Participate in Research~~ Adult Research Consent Form and Parent/Legal Guardian Permission Form<br><br>Added:<br>The word "you" throughout this form refers to you or your child.<br>* Adult consent form and parent/legal guardian permission form were combined into one document | CMS Studies Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 2 added the sentence:<br>Your data may be shared with other researchers for future research studies. However, the data that is shared will not include any information that could identify you. | CMS Studies Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| End of Section 3 added:<br>You will not directly receive any results generated from this research. | CMS Studies Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 8:<br>Deleted name of IRB Administrator and changed "Patient Services Coordinator" to "BMT Patient Navigator" and inserted the sentence at the end "(Enter Transplant Center office of research subject advocacy contact information)." | CMS Studies Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| New CMS assent form created | CMS Studies Minor Assent Ages 7 - 11 | 07/30/2019 |
| New CMS assent form created | CMS Studies Minor Assent Ages 12 - 17 | 07/30/2019 |
| Just under title:<br>*Adult ~~Marrow Toxic Injury~~ Research Consent Form and Parent/Legal Guardian Permission Form<br>Marrow Toxic Injury Patient<br><br>Added:<br>The word "you" throughout this form refers to you or your child.<br><br>* Adult consent form and parent/legal guardian permission form were combined into one document | Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 2, last sentence, first paragraph:<br>If you agree to take part in the Research Database, your data will be used in research studies; however, the data that is used will not include any information that could identify you. | Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 3, second paragraph, second sentence:<br>~~Both the hospital and clinic where you are being treated~~ Your treatment center | Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form | 07/30/2019 |

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| Section 5 added:<br>Your data may be used for commercial projects and profit. If your data is used for commercial projects, you will not share in any profit. | Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 8:<br>Added to first paragraph: *(Treatment Center Physician) (telephone number).*<br><br>Added to second paragraph: *(Enter Transplant Center office of research subject advocacy contact information)*. | Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Just under title:<br>*Adult ~~Allogeneic Recipient~~ Research Consent Form and Parent/Legal Guardian Permission Form<br>Allogeneic Recipient<br><br>Added:<br>The word "you" throughout this form refers to you or your child.<br><br>* Adult consent form and parent/legal guardian permission form were combined into one document | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 2, first paragraph, 2nd sentence:<br>These medical data may include medical records ~~claims~~ data such as ~~the billing codes for procedures~~ diagnosis or procedure codes, and test~~s~~ or health care services that your treatment center ~~submits to insurance companies for payment~~ provides. | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 2, second paragraph, first sentence:<br>Your transplant-related or cellular therapy-related data may be shared with ~~investigators~~ researchers, collaborating organizations, or other registries outside the CIBMTR. The data that is shared will not include any information that could identify you. ~~but no identifying information will be given to those investigators.~~ | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/19 |
| Section 3, third paragraph, second sentence:<br>You will not directly receive any results generated from this research. | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 5, third sentence:<br>Your data may be used for commercial projects and profit. If your data is used for commercial projects, you will not share in any profit. | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 8, first paragraph, last sentence:<br>By checking the "AGREE" box below, you are only agreeing to give the CIBMTR your contact information and preferred language, so that the CIBMTR can contact you to tell you about the study.<br><br>Added a line for Preferred Language | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |

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| Section 9, first paragraph, first sentence:<br>... Dr. Douglass Rizzo, Senior ~~Associate~~ Scientific Director... | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 9, second paragraph, first sentence:<br>... please contact ~~Roberta King~~, the NMDP IRB Administrator...<br><br>Second sentence:<br>... please contact ~~Patient Service Coordinator~~ BMT Patient Navigator with Be The Match Patient ~~and Health Professional~~ Services at 1-888-999-6743 or patientinfo@nmdp.org or (*Enter Transplant Center office of research subject advocacy contact information*). | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 10<br>Recipient/Subject Signature *(if 18 years or older)*<br><br>Added lines for printed name and signature of parent/legal guardian | Recipient Allo Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Just under title:<br>*Adult ~~Autologous Recipient~~ Research Consent Form and Parent/Legal Guardian Permission Form<br>Autologous Recipient<br><br>Added:<br>The word "you" throughout this form refers to you or your child.<br><br>* Adult consent form and parent/legal guardian permission form were combined into one document | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 2, fourth paragraph, second sentence:<br>These medical data may include medical records ~~claims~~ data such as ~~the billing codes for procedures~~ diagnosis or procedure codes, and test~~s~~ or health care services that your treatment center ~~submits to insurance companies for payment~~ provides. | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 2, fourth paragraph, first sentence:<br>Your transplant-related or cellular therapy-related data may be shared with ~~investigators~~ researchers, collaborating organizations, or other registries outside the CIBMTR. The data that is shared will not include any information that could identify you. ~~but no identifying information will be given to those investigators.~~ | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 3, third paragraph, second sentence:<br>You will not directly receive any results generated from this research. | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 5, third sentence:<br>Your data may be used for commercial projects and profit. If your data is used for commercial projects, you will not share | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |

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| in any profit. | | |
| Section 8, first paragraph, last sentence:<br>By checking the "AGREE" box below, you are only agreeing to give the CIBMTR your contact information and preferred language, so that the CIBMTR can contact you to tell you about the study.<br><br>Added a line for Preferred Language | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 6, first paragraph, last sentence:<br>... or any other services that ~~it is your right~~ you have a right to receive... | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 9, first paragraph, first sentence:<br>... Dr. Douglass Rizzo, Senior ~~Associate~~ Scientific Director... | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 9, second paragraph, first sentence:<br>... please contact ~~Roberta King~~, the NMDP IRB Administrator...<br><br>Second sentence:<br>... please contact ~~Patient Service Coordinator~~ BMT Patient Navigator with Be The Match Patient ~~and Health Professional~~ Services at 1-888-999-6743 or patientinfo@nmdp.org or (*Enter Transplant Center office of research subject advocacy contact information*). | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Section 10<br>Recipient/Subject Signature *(if 18 years or older)*<br><br>Added lines for printed name and signature of parent/legal guardian | Recipient Auto Adult/Parent Legal Guardian Consent Form | 07/30/2019 |
| Underneath the title:<br>Minor ~~Allogeneic Recipient~~ Assent Form (7 to 11 years of age)<br>Allogeneic or Autologous Recipient<br><br>* Minor allo/auto assent forms for ages 7 - 11 were combined into one document | Recipient Minor Assent Form (7 - 11) | 07/30/2019 |
| Underneath the title:<br>Minor ~~Allogeneic Recipient~~ Assent Form (12 to 17 years of age)<br>Allogeneic or Autologous Recipient<br><br>* Minor allo/auto assent forms for ages 12 - 17 were combined into one document | Recipient Minor Assent Form (12 - 17) | 07/30/2019 |
| Deleted the paragraph:<br>Your transplant or cellular therapy will be registered with the CIBMTR. As part of this process, your Social Security Number, mother's maiden name, and location of birth are used to make a unique identification number. This number is | Recipient Minor Assent Form (12 - 17) | 07/30/2019 |

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| used when your medical information is sent to the CIBMTR. If you are concerned about giving information like your Social Security Number, please discuss this with your parent or legal guardian. | | |
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| GRID line added to footer of consent form. | **Donor Consent Form (footer):** Adult Donor Unrelated | 05/15/2019 |
| After "I AGREE" checkbox, added lines for Name, Mailing Address, Email Address, and Phone Number (cell or landline) | **Recipient Consent Forms (Section VIII):** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian | 07/30/2018 |
| 1st paragraph, last sentence: "By checking the 'AGREE' box below, you are only agreeing <u>to give the CIBMTR your contact information so</u> that the CIBMTR can contact you to tell you about the study." | **Recipient Consent Forms (Section VIII):** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian | 07/30/2018 |
| 2nd paragraph, 1st sentence: "Your transplant-related or cellular therapy-related data may be shared with investigators, <u>collaborating organizations,</u> or other registries…" | **Recipient Consent Forms (Section II):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian<br><br>Adult Autologous Recipient; Minor Autologous Recipient Parent/Legal Guardian (Section II, 5th paragraph, 1st sentence) | 07/30/2018 |
| 1st paragraph, added 2nd sentence: "<u>These medical data may include medical claims data such as the billing codes for procedures, tests or healthcare services that your treatment center submits to insurance companies for payment.</u>" | **Recipient Consent Forms (Section II):** Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian<br><br>Adult Autologous Recipient; Minor Autologous Recipient Parent/Legal Guardian (Section II, 4th paragraph, 2nd sentence) | 07/30/2018 |
| Added 3rd bullet point: "<u>Determine how a donor's or recipient's genetics impact recipient recovery after a</u> | **Donor Consent Form (Section I):** | 07/30/2018 |

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| transplant or cellular therapy." | Adult Donor<br><br>**Recipient Consent Forms (Section I):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian | |
| 1st paragraph: "The Center for International Blood and Marrow Transplant Research (CIBMTR), ~~the~~ a research ~~program~~ collaboration of the National Marrow Donor program (NMDP)/Be The Match and the Medical College of Wisconsin." | **Donor Consent Form (Section I):**<br>Adult Donor<br><br>**Recipient Consent Forms (Section I):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br><br>**Marrow Toxic Injury Consent Forms (Section I):**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian<br><br>**CMS Studies Consent Form (Section I):**<br>Adult CMS Studies | 07/30/2018 |
| Last paragraph: "Additionally, ~~systems and applications within the NMDP are certified by the Health Resources Services Administration Office of Information and Technology.~~ NMDP maintains 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." | **Protocol**: Section 10 | 07/30/2018 |
| Added 6th paragraph: "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." | **Protocol**: Section 10 | 07/30/2018 |
| 4th paragraph: "…the unique identification number is | **Protocol**: Section 10 | 07/30/2018 |

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| assigned to ensure that the participant has not been previously registered by another center. On a subset of patients that provide additional consent to be contacted directly by CIBMTR, address, phone number and email address will also be collected. These identifying data are stored in a secure ~~database~~ table that can only be accessed by two authorized individuals. ~~that is totally separated from the Research Database~~." | | |
| Added entire Section 9. Participant Contact Information | **Protocol**: Section 9 | 07/30/2018 |
| 1st paragraph: "Once the study has been approved, the NMDP ~~and the MCW~~ IRB ~~are~~ is informed of new studies…" | **Protocol**: Section 7.2 | 07/30/2018 |
| Added entire Section 6. Collaborations with Other Organizations | **Protocol**: Section 6 | 07/30/2018 |
| "In no cases would the recipient, individual with a marrow toxic injury or donor be contacted in order to obtain additional data without IRB approval for the specific study and IRB-approved consent from the participant for the specific study." | **Protocol**: Section 4.4 | 07/30/2018 |
| Last paragraph: "…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 recipient." | **Protocol**: Section 4.3 | 07/30/2018 |
| 1st paragraph: "~~Transplant~~ Treatment Center staff…" | **Protocol**: Section 4.3 | 07/30/2018 |
| 1st paragraph: "~~Transplant~~ Treatment Centers complete the forms at the following time-points." | **Protocol**: Section 4.2 | 07/30/2018 |
| Added to data collected annually starting year three:<br>"Quality of life" | **Protocol**: Table in Section 4.1 | 07/30/2018 |
| Added to data collected at 100 days, six months, one year, two year, post-transplant or cellular therapy:<br>"Quality of life" | **Protocol**: Table in Section 4.1 | 07/30/2018 |
| "100 days, six months, one year, two year, post-transplant or cellular therapy" | **Protocol**: Table in Section 4.1 | 07/30/2018 |
| Added to data collected at the time of transplant or cellular therapy:<br>"Pre-transplant or cellular therapy disease-specific data such as blood counts, disease status, cytogenetics"<br>"Co-existing disease at the time of transplant or cellular therapy"<br>"HSC or cellular therapy product manipulation"<br>"Quality of life" | **Protocol**: Table in Section 4.1 | 07/30/2018 |
| "At the time of transplant or cellular therapy" | **Protocol**: Table in Section 4.1 | 07/30/2018 |
| Added to data collected at registration: "If patient provides written consent to collect contact information, the following will also be collected: Address, Phone numbers, Email address" | **Protocol**: Table in Section 4.1 | 07/30/2018 |
| 1st paragraph: "Recipient data are collected from pre-existing data within the recipient's medical record chart at the ~~transplant~~ treatment center. ~~Transplant~~ Treatment Centers complete the forms at the following time-points." | **Protocol**: Section 4.1 | 07/30/2018 |
| 1st paragraph: "All U.S. centers must have an IRB-approved protocol and consent forms prior to submitting data about transplant or cellular therapy recipients, ~~transplant~~ donors, or individuals with marrow toxic injury…" | **Protocol**: Section 3 | 07/30/2018 |

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| "All donors registered on the NMDP Registry, regardless of whether they ~~who~~ have been requested to donate a product…" | **Protocol**: Section 2.3 | 07/30/2018 |
| 5th bullet point; 4th paragraph: "How access to transplantation or cellular therapy for different groups of patients can be improved, including studies designed to understand the financial or economic impact of transplant or studies designed to inform insurance/government payer policy, such as U.S. Medicare policy" | **Protocol**: Section 1.3 | 07/30/2018 |
| Added 4th bullet point; 4th paragraph: "Molecular explanations for histocompatibility or clinical outcome revealed through analysis of genomic, epigenetic, or other biomolecular data" | **Protocol**: Section 1.3 | 07/30/2018 |
| 4th paragraph: "The ~~primary~~ purpose of the Research Database is to have a comprehensive source of observational data that can be used to study HC transplantation~~. A~~ as well as ~~secondary purpose of the database is~~ to have a comprehensive source of data to study ~~marrow toxic injuries and~~ the application of hematopoietic cells for regenerative medicine or immune-based therapy, including for malignancy or infection and marrow toxic injuries. Researchers whose study proposals are reviewed and approved in advance by the CIBMTR may use data for studies examining HC transplantation and its effects on recipients and donors, to study ~~marrow toxic injury, or to~~ regenerative medicine or immune-based therapy, including for malignancy or infection or marrow toxic injuries." | **Protocol**: Section 1.3 | 07/30/2018 |
| 2nd paragraph: "~~Secondary~~ More recent goals of the CIBMTR Research program…" | **Protocol**: Section 1.3 | 07/30/2018 |
| 1st paragraph: "The ~~primary~~ original goal of the CIBMTR Research Program…" | **Protocol**: Section 1.3 | 07/30/2018 |
| 1st paragraph: "The CIBMTR is a~~n~~ research affiliation between the NMDP and the Medical College of Wisconsin." | **Protocol:** Section 1.2 | 07/30/2018 |
| Added Section 6 Collaborating with other Organizations and Section 9 Participant Contact Information to Table of Contents | **Protocol:** Page 2 Table of Contents | 07/30/2018 |
| Protocol version date and number changed to July 2018, Version 8.0. | **Protocol:** Title page | 07/30/2018 |
| Paragraph 1, last sentence: "If you agree to take part in the Research Database, these data that have already been collected will be ~~available to researchers through the CIBMTR~~ used in research studies." | **Donor Consent Form (Section II):**<br>Adult Donor | 01/23/2018 |
| After paragraph 3: "This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify your child 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 you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, | **Recipient Consent Forms (Section IV):**<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br><br>**Marrow Toxic Injury Consent Forms (Section IV):**<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 01/23/2018 |

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| or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your child's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.<br><br>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 that is needed for auditing or program evaluation by Health Resources and Services Administration (HRSA) or National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about your child or your child's involvement in this research. If you want your child's research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.<br><br>To expand research, it is helpful for researchers to share information they get from studying health information. They do this by putting the information into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to allow your child take part in the Research Database, some of your child's health information may be placed into scientific databases that can be accessed by researchers outside the CIBMTR. Researchers may be able to see and use your child's information pooled with information from many other individuals, but your child's name and other information that could directly identify your child will never be placed into a scientific database. " | | |
| After paragraph 3: Added "This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you 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 you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child | **Recipient Consent Forms (Section IV):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br><br>**Marrow Toxic Injury Consent Forms (Section IV):**<br>Adult Marrow Toxic Injury;<br><br>**CMS Studies Consent Form (Section IV):**<br>Adult CMS Studies | 01/23/2018 |

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| abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.<br><br>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 that is needed for auditing or program evaluation by Health Resources and Services Administration (HRSA) or National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.<br><br>To expand research, it is helpful for researchers to share information they get from studying health information. They do this by putting the information into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in the Research Database, some of your health information may be placed into scientific databases that can be accessed by researchers outside the CIBMTR. Researchers may be able to see and use your information pooled with information from many other individuals, but your name and other information that could directly identify you will never be placed into a scientific database." | **Donor Consent Form (Section IV):**<br>Adult Donor | |
| Paragraph 4: "Your treatment center will send medical data about your disease and your transplant or cellular therapy that is collected prior to your transplant or cellular therapy to the CIBMTR. If you agree to take part in the Research Database, y~~Y~~our doctor will send additional data to the CIBMTR ~~before and~~ after your transplant or cellular therapy…" | **Recipient Consent Form (Section II):**<br>Adult Autologous Recipient | 07/30/2017 |
| Paragraph 4: "Your child's treatment center will send medical data about your child's disease and his/her transplant or cellular therapy that is collected prior to his/her transplant or cellular therapy to the CIBMTR. If your child agrees to participate, and you allow your child to take part in the Research Database, y~~Y~~our child's doctor will send additional data to the CIBMTR ~~before and~~ after your child's transplant or cellular therapy…" | **Recipient Consent Form (Section II):**<br>Minor Autologous Recipient Parent/Legal Guardian | 07/30/2017 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| Paragraph 3: "~~If you take part in the Research Database, y~~Your transplant or cellular therapy will be registered with the CIBMTR." | **Assent Form:**<br>Minor Auto Assent 12-17 | 07/30/2017 |
| Added a new consent form titled: Prospective Assessment of Allogeneic Hematopoietic Cell Transplantation in Patients with Medicare Coverage | **New Consent Form** | 02/08/2017 |
| Added Section 6.3 Studies Designed to Inform U.S. Medicare Policy | **Protocol:** Section 6.3 | 02/08/2017 |
| Added to 4th bullet point: How access to transplantation or cellular therapy for different groups of patients can be improved, <u>including studies designed to inform insurance/government payer policy, such as U.S. Medicare policy;</u> | **Protocol:** Section 1.3 | 02/08/2017 |
| Changed NMDP's address | **Protocol:** Title page | 07/30/2016 |
| Paragraph 1: Deleted last sentence, "~~Annually, more than 5,000 patients initiate an active donor search through the NMDP, and over 3,000 of these searches result in transplants~~." | **Protocol:** Section 1.1 | 07/30/2016 |
| Paragraph 1: "Although the exact studies for which Research Database data may be used ~~is~~ <u>are</u> not known at this time…" | **Donor Consent Forms (Section I):**<br>Adult Donor<br>**Recipient Consent Forms (Section I, paragraph 2):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms (Section I, paragraph 2):**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 07/30/2016 |
| Paragraph 1, 1st sentence: "~~If you agree to take part in the Research Database, y~~Your transplant or cellular therapy will be registered with the CIBMTR." | **Recipient Consent Forms (Section II):**<br>Adult Autologous Recipient;<br>Minor Autologous Recipient Parent/Legal Guardian | 07/30/2016 |
| Paragraph 2: Updated NMDP's address | **Donor Consent Forms (Section IX):**<br>Adult Donor | 07/30/2016 |
| Added 2nd sentence: "<u>Whenever possible, patients should be informed about the protocol and asked to provide consent to participate prior to the transplant. In the rare circumstance where that is not possible, it is acceptable to obtain the patient's consent after the transplant has occurred.</u>" | **Protocol:** Section 2.4 | 07/30/2015 |
| Branding changes were applied to all consent and assent forms to remove references to NMDP (i.e., | **Donor Consent Forms:**<br>Adult Donor | 07/30/2014 |

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| ~~NMDP/~~CIBMTR). | **Recipient Consent Forms:**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms:**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian<br>**Assent Forms:**<br>Minor Allo Assent 7-11;<br>Minor Allo Assent 12-17;<br>Minor Auto Assent 7-11;<br>Minor Auto Assent 12-17;<br>Minor Marrow Toxic Injury Assent 7-11;<br>Minor Marrow Toxic Injury Assent 12-17 | |
| Paragraph 1: "The ~~National Marrow Donor Program (NMDP) and the~~ Center for International Blood and Marrow Transplant Research (CIBMTR), the research program of the National Marrow Donor Program (NMDP)/Be The Match, invites you to take part in a Research Database." | **Donor Consent Forms (Section I):**<br>Adult Donor<br>**Recipient Consent Forms (Section I):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient<br>**Marrow Toxic Injury Consent Forms (Section I):**<br>Adult Marrow Toxic Injury | 07/30/2014 |
| Paragraph 1: "The ~~National Marrow Donor Program (NMDP) and the~~ Center for International Blood and Marrow Transplant Research (CIBMTR), the research program of the National Marrow Donor Program (NMDP)/Be The Match, invites your child to take part in a Research Database." | **Recipient Consent Forms (Section I):**<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms (Section I):**<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 07/30/2014 |
| Paragraph 1: "…will be available to researchers through the CIBMTR." | **Donor Consent Forms (Section II):**<br>Adult Donor | 07/30/2014 |
| "…all research studies using these data must first be approved by a group of scientists within the ~~NMDP/~~CIBMTR. ~~NMDP~~ The proposed study will also be reviewed ~~the proposed study~~ to make sure the research is consistent with the types of studies described above." | **Donor Consent Forms (Section II):**<br>Adult Donor<br>**Recipient Consent Forms (Section II):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian; | 07/30/2014 |

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| | Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms (Section II):**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | |
| "Your donor center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…" | **Donor Consent Forms (Section IV):**<br>Adult Donor | 07/30/2014 |
| "Your treatment center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…" | **Recipient Consent Forms (Section IV):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient<br>**Marrow Toxic Injury Consent Forms (Section IV):**<br>Adult Marrow Toxic Injury | 07/30/2014 |
| "Your child's treatment center and the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…" | **Recipient Consent Forms (Section IV):**<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms (Section IV):**<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 07/30/2014 |
| "Web site" was changed to one word "website". | **Donor Consent Forms (Section IV):**<br>Adult Donor<br>**Recipient Consent Forms (Section IV):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms (Section IV):**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 07/30/2014 |
| "~~NMDP~~ Be The Match Donor Advocacy" | **Donor Consent Forms (Section VIII):**<br>Adult Donor | 07/30/2014 |
| Paragraph 2: References to "NMDP" were changed to "Be The Match". | **Donor Consent Forms (Section IX):**<br>Adult Donor | 07/30/2014 |
| Paragraph 2: "Due to the need to follow-up with you after your transplant or cellular therapy, please tell your ~~transplant~~ treatment center if your contact information changes." | **Recipient Consent Forms (Section VIII):**<br>Adult Allogeneic Recipient; | 07/30/2014 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| | Adult Autologous Recipient | |
| Paragraph 2: "Due to the need to follow-up with you after your child's transplant <u>or cellular therapy</u>, please tell your ~~transplant~~ <u>treatment</u> center if your contact information changes." | **Recipient Consent Forms (Section VIII):**<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian | 07/30/2014 |
| Paragraph 2: "…with Be the Match® Patient <u>and Health Professional</u> Services…" | **Recipient Consent Forms (Section IX):**<br>Adult Allogeneic Recipient;<br>Adult Autologous Recipient;<br>Minor Allogeneic Recipient Parent/Legal Guardian;<br>Minor Autologous Recipient Parent/Legal Guardian<br>**Marrow Toxic Injury Consent Forms (Section VIII):**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 07/30/2014 |
| Removed ~~National Marrow Donor Program~~ from title page | **Protocol:** Title Page | 07/30/2014 |
| Paragraph 2, 1st sentence: "…data may be shared with investigators <u>or other registries</u> outside the NMDP/CIBMTR…" | **Recipient Consent Forms (Section II):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient (paragraph 4);<br>Minor Auto Recipient Parent/Legal Guardian (paragraph 4); | 07/30/2013 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| New Section VIII with the following wording:<br>PERMISSION TO CONTACT FOR FUTURE CIBMTR RESEARCH STUDIES<br>Do you agree to give the CIBMTR permission to contact you in the future to tell you about research studies for which you are eligible? These studies are different from the studies that use your medical data. These studies would involve you directly, for example, asking you to complete a survey. You may decide if you want to participate in a specific study when you are contacted. By checking the "AGREE" box below, you are only agreeing that the CIBMTR can contact you to tell you about the study.<br><br>Due to the need to follow-up with you after your transplant, please tell your transplant center if your contact information changes. If the contact information on file is no longer valid, it might be necessary to use an internet-based search service to find you. By agreeing to be contacted for future studies, you authorize the CIBMTR to use such a service to search public and non-public information only for the purpose of trying to locate you.<br><br>☐ I AGREE to allow CIBMTR to contact me about future studies.<br>☐ I DO NOT want CIBMTR to contact me about future studies. | **Recipient Consent Forms (Section VIII):**<br>Adult Allo Recipient;<br>Adult Auto Recipient | 07/30/2013 |
| New Section VIII with the following wording:<br>PERMISSION TO CONTACT FOR FUTURE CIBMTR RESEARCH STUDIES<br>Do you agree to give the CIBMTR permission to contact you in the future to tell you about research studies for which your child is eligible? These studies are different from the studies that use your child's medical data. These studies would involve your child directly, for example, asking you or your child to complete a survey. You may decide if you want your child to participate in a specific study when you are contacted. By checking the "AGREE" box below, you are only agreeing that the CIBMTR can contact you to tell you about the study.<br><br>Due to the need to follow-up with you after your child's transplant, please tell your transplant center if your contact information changes. If the contact information on file is no longer valid, it might be necessary to use an internet-based search service to find you. By agreeing to be contacted for future studies, you authorize the CIBMTR to use such a service to search public and non-public information only for the purpose of trying to locate you.<br>☐ I AGREE to allow CIBMTR to contact me about future studies for which my child is eligible. | **Recipient Consent Forms (Section VIII):**<br>Minor Allo Recipient Parent/Legal Guardian;<br>Minor Auto Recipient Parent/Legal Guardian | 07/30/2013 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| ☐ I DO NOT want CIBMTR to contact me about future studies. | | |
| Paragraph 1, subheading: "Registering Your Child's Transplant or Cellular Therapy" | **Recipient Consent Forms (Section II):** Minor Auto Recipient Parent/Legal Guardian | 07/30/2013 |
| Paragraph 4, 3rd sentence: "…and its effects on recipients and donors ~~or~~ to study marrow toxic injury, or to study regenerative medicine or immune-based therapy, including for malignancy or infection." | **Protocol:** Section 1.3 | 09/06/2012 |
| Page 4 bullet points:<br>• How well recipients recover from their transplants or cellular therapy;<br>• How recovery after transplantation or cellular therapy can be improved;<br>• Long-term outcomes after transplantation or cellular therapy,<br>• How access to transplantation or cellular therapy for different groups of patients can be improved | **Protocol:** Section 1.3 | 09/06/2012 |
| 1st sentence: "…bone marrow or cord blood) or any recipient of cellular therapy in a CIBMTR center is eligible…" | **Protocol:** Section 2.1 | 09/06/2012 |
| Inserted 4th paragraph: "CIBMTR will share data with the United States Immunodeficiency Network (USIDNET) for inclusion in the USIDNET database for use in future research as determined by USIDNET. Only data from recipients who are enrolled in both the USIDNET database protocol and the CIBMTR Research Database protocol will be exchanged with USIDNET." | **Protocol:** Section 5 | 09/06/2012 |
| Last paragraph, 1st sentence: "The CIBMTR may also engage in discrete studies with other registries…" | **Protocol:** Section 5 | 09/06/2012 |
| Last paragraph, 3rd sentence: "~~Examples~~ An example of ~~these registries are~~ this type of registry is the ~~United States Immunodeficiency Network (USIDNET) or the~~ End Stage Renal Disease (ESRD) Network." | **Protocol:** Section 5 | 09/06/2012 |
| Last paragraph, last sentence: "…will require ~~IRB approval by the NMDP IRB~~ administrative approval by the NMDP IRB Chair or designated NMDP IRB member." | **Protocol:** Section 5 | 09/06/2012 |
| Paragraph 1, last sentence: "…transplant or other cellular therapy."<br>Paragraph 2, 1st sentence: "…transplants and other cellular therapies work well."<br>Paragraph 2, 2nd sentence: "…had a transplant or other cellular therapy."<br>Paragraph 3, 1st sentence: "…your transplant or cellular therapy will be registered…"<br>Paragraph 4, 1st sentence: "…about your transplant or cellular therapy and how you do after the transplant or cellular therapy and send it…"<br>Paragraph 4, 3rd sentence: "…ways to make transplants and other cellular therapies work better."<br>Paragraph 4, last sentence: "You will have a transplant or cellular therapy for your disease…" | **Minor Assent Forms:** Minor Auto Recipient Assent (12 to 17); | 7/30/2012 |

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| Paragraph 5, last sentence: "…how to make transplants and other cellular therapies work better in the future." | | |
| Paragraph 1, last sentence: "…transplant, or cellular therapy."<br>Paragraph 2, 1st sentence: "…transplants and other cellular therapies work well."<br>Paragraph 2, 2nd sentence: "…had a transplant or other cellular therapy."<br>Paragraph 3, 1st sentence: "…about your transplant or cellular therapy and how you do after the transplant or cellular therapy and send it…"<br>Paragraph 3, 3rd sentence: "…ways to make transplants and cellular therapies work better."<br>Paragraph 3, last sentence: "You will have a transplant or cellular therapy for your disease…"<br>Paragraph 4, last sentence: "…how to make transplants and other cellular therapies work better in the future." | **Minor Assent Forms:**<br>Minor Allo Recipient Assent (12 to 17); | 7/30/2012 |
| Paragraph 1, 2nd sentence: "…transplants and cellular therapies work."<br>Paragraph 2, 1st sentence: "…transplant or cellular therapy goes."<br>Paragraph 2, 2nd sentence: "…your transplant or cellular therapy."<br>Paragraph 2, last sentence: "…transplant or cellular therapy anyway."<br>Paragraph 3, last sentence: "…need a transplant or cellular therapy."<br>Paragraph 4, 1st sentence: "…your transplant or cellular therapy." | **Minor Assent Forms:**<br>Minor Allo Recipient Assent (7 to 11);<br>Minor Auto Recipient Assent (7 to 11) | 7/30/2012 |
| Paragraph 1: "…(~~Transplant~~ Treatment Center Physician)…" | **Recipient Consent Forms (Section VIII):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 2, 2nd sentence: "…Patient Services Coordinator with ~~the NMDP Office of Patient Advocacy~~ Be the Match® Patient Services at…" | **Recipient Consent Forms (Section VIII):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian;<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 7/30/2012 |
| Sentence 2: "…~~planned treatment~~ transplant or cellular therapy, but…" | **Recipient Consent Forms (Section VII):**<br>Minor Auto Recipient Parent/Legal Guardian; | 7/30/2012 |
| Sentence 2: "…transplant or cellular therapy as | **Recipient Consent Forms** | 7/30/2012 |

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| scheduled…" | **(Section VII):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Adult Auto Recipient; | |
| Paragraph 2, last sentence: "…~~hospital or clinic~~ treatment center…" | **Recipient Consent Forms (Section VI):**<br>Minor Auto Recipient<br>Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 2, last sentence: "…~~transplant~~ treatment center…" | **Recipient Consent Forms (Section VI):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Adult Auto Recipient; | 7/30/2012 |
| Paragraph 1, 1st sentence: "…~~transplant~~ treatment center…"<br>Paragraph 2, 1st sentence: "…~~transplant~~ treatment center…" | **Recipient Consent Forms (Section IV):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient<br>Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 2, 2nd sentence: "…~~transplant~~ treatment center…" | **Recipient Consent Forms (Section III):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 2, 1st sentence: "…transplant or cellular therapy."<br>Paragraph 3: "…transplant or cellular therapy with the…"<br>Paragraph 4, 1st sentence: "…~~transplant~~ treatment center will send…"<br>Paragraph 4, 1st sentence: "…transplant or cellular therapy to the NMDP/CIBMTR."<br>Paragraph 4, 2nd sentence: "…transplant or cellular therapy, and once a year…" | **Recipient Consent Forms (Section II):**<br>Adult Auto Recipient;<br>Minor Auto Recipient<br>Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 2, 1st sentence: "...transplant-related or cellular therapy-related data may be shared…" | **Recipient Consent Forms (Section II):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 1, 2nd sentence: "…transplant or cellular therapy, and once a year…" | **Recipient Consent Forms (Section II):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 1, 1st sentence: "…transplant or cellular therapy will be…" | **Recipient Consent Forms (Section II):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient | 7/30/2012 |

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| | Parent/Legal Guardian; | |
| Added Paragraph 3: "A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. (Identifier: NCT01166009)" | **Donor Consent Form (Section IV):**<br>Adult Donor<br>**Recipient Consent Forms (Section IV):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian;<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 7/30/2012 |
| Paragraph 1, last sentence: "The NMDP/CIBMTR ~~will try hard to make sure~~ has procedures in place so that no one outside the NMDP/CIBMTR will know…" | **Donor Consent Form (Section IV):**<br>Adult Donor<br>**Recipient Consent Forms (Section IV):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian;<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 7/30/2012 |
| Paragraph 3, last sentence: "…who need a transplant or cellular therapy." | **Donor Consent Form (Section III):**<br>Adult Donor<br>**Recipient Consent Forms (Section III):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian; | 7/30/2012 |
| Paragraph 1, 2nd sentence: "…important to the transplant or cellular therapy." | **Donor Consent Form (Section II):**<br>Adult Donor | 7/30/2012 |
| Paragraph 2, 1st sentence: "…transplants and other cellular therapies work well." | **Recipient Consent Forms (Section I):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian; | 7/30/2012 |
| Sentence 2: "…patients who have had a transplant or other cellular therapy and donors who donate…" | **Donor Consent Form (Section I):** | 7/30/2012 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| Sentence 3: "…transplants and other cellular therapies work better."<br>Bullet 1: "…from their transplant or cellular therapy;"<br>Bullet 2: "…after a transplant or cellular therapy can be…"<br>Bullet 3: "…to transplant or cellular therapy for different." | Adult Donor<br>**Recipient Consent Forms (Section I):**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian; | |
| Consent Form Title: "Research Database for Hematopoietic ~~Stem~~ Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries" | **Recipient Consent Forms:**<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian<br>**Minor Assent Forms:**<br>Minor Marrow Toxic Injury Assent (7 to 11);<br>Minor Marrow Toxic Injury Assent (12 to 17) | 7/30/2012 |
| Consent Form Title: "Research Database for Hematopoietic ~~Stem~~ Cell Transplantation and Cellular Therapies" | **Donor Consent Form:**<br>Adult Donor<br>**Recipient Consent Forms:**<br>Adult Allo Recipient;<br>Minor Allo Recipient Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian;<br>**Minor Assent Forms:**<br>Minor Allo Recipient Assent (7 to 11);<br>Minor Allo Recipient Assent (12 to 17);<br>Minor Auto Recipient Assent (7 to 11);<br>Minor Auto Recipient Assent (12 to 17); | 7/30/2012 |
| Paragraph 4, 1st sentence: "Recipients of ~~T~~transplant ~~recipients~~ or hematopoietic cells for regenerative medicine or immune-based therapy, including for malignancy or infection, and individuals with marrow toxic injury…" | **Protocol:** Section 8 | 7/30/2012 |
| Deleted paragraph 2: "~~All maternal cord blood donors are enrolled in the NMDP Cord Blood Bank Investigational New Drug (IND) protocol, and sign an informed consent document specific to that protocol. Data collected as part of the Cord Blood Bank protocol are included in the Research Database.~~" | **Protocol:** Section 2.3 | 7/30/2012 |
| Sentence 1: "…transplant (includes cells collected from peripheral blood, bone marrow or cord blood) in a CIBMTR center…" | **Protocol:** Section 2.1 | 7/30/2012 |
| Paragraph 4: Added last bullet "The application and success of hematopoietic cells for regenerative medicine or immune-based therapy, including for malignancy or infection" | **Protocol:** Section 1.3 | 7/30/2012 |
| Paragraph 4, 2nd sentence: "…marrow toxic injuries and the | **Protocol:** Section 1.3 | 7/30/2012 |

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| application of hematopoietic cells for regenerative medicine or immune-based therapy, including for malignancy or infection." | | |
| Paragraph 2, 1st sentence: ~~A s~~Secondary goals of the CIBMTR Research Program are to understand uses of hematopoietic cells for regenerative medicine or immune-based therapy, including for malignancy or infection, and ~~is~~ to improve treatments…" | **Protocol:** Section 1.3 | 7/30/2012 |
| Paragraph 2: Added last sentence, "In 2011 CIBMTR activities were expanded to include uses of hematopoietic cells for regenerative medicine or immune-based therapy, including for malignancy or infection." | **Protocol:** Section 1.2 | 7/30/2012 |
| "(H~~S~~C)" | **Protocol:** throughout | 7/30/2012 |
| "…hematopoietic ~~stem~~ cell…" | **Protocol:** throughout | 7/30/2012 |
| 2.1: Recipient ~~and Marrow Toxic Injury~~ Eligibility Criteria<br>2.2: Individuals with Marrow Toxic Injury Eligibility Criteria<br>2.3: Unrelated Donor Eligibility Criteria<br>4.3: Collection of Unrelated Donor Data<br>5: ~~Exchange of Data~~ Collaboration with Other Registries | **Protocol:** Page 2 Table of Contents | 7/30/2012 |
| Title change: Protocol for a Research Database for Hematopoietic ~~Stem~~ Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries | **Protocol:** Title page | 7/30/2012 |
| Paragraph 1: Last sentence "You are being asked to participate in this database because you have been…" | **Minor Assent Forms:**<br>Minor Marrow Toxic Injury Assent (12 to 17) | 7/30/2011 |
| Paragraph 6: 2nd sentence "Your doctors or your parents ~~cannot~~ will not make you be in…" | **Minor Assent Forms:**<br>Minor Auto Recipient Assent (12 to 17) | 7/30/2011 |
| Paragraph 5: 2nd sentence "Your doctors or your parents ~~cannot~~ will not make you be in…" | **Minor Assent Forms:**<br>Minor Allo Recipient Assent (12 to 17);<br>Minor Marrow Toxic Injury Assent (12 to 17) | 7/30/2011 |
| Paragraph 2: Last sentence "…he/she is agreeing to these ~~audits~~ reviews, which may include copying… | **Recipient Consent Forms (Section IV):**<br>Minor Allo Recipient Parent/Legal Guardian | 7/30/2011 |
| Paragraph 2: Last sentence "…you agree to these ~~audits~~ reviews, which may include copying… | **Donor Consent Form (Section IV):**<br>Adult Donor<br>**Recipient Consent Forms (Section IV):**<br>Adult Allo Recipient;<br>Adult Auto Recipient;<br>Minor Auto Recipient Parent/Legal Guardian;<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury Parent/Legal Guardian | 7/30/2011 |
| Paragraph 2: Added wording to last sentence "No identifiable information about your child will be given to the researchers, nor will it be published or presented at scientific | **Recipient Consent Forms (Section III):**<br>Minor Allo Recipient | 7/30/2011 |

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| meetings." | Parent/Legal Guardian;<br>Minor Auto Recipient<br>Parent/Legal Guardian;<br>Minor Marrow Toxic Injury<br>Parent/Legal Guardian | |
| Paragraph 2: Added wording to last sentence "No identifiable information about you will be <u>given to the researchers, nor will it be</u> published or presented at scientific meetings." | **Donor Consent Form (Section III):**<br>Adult Donor<br>**Recipient Consent Forms (Section III):**<br>Adult Allo Recipient;<br>Adult Auto Recipient;<br>Adult Marrow Toxic Injury; | 7/30/2011 |
| Added ClinicalTrials.gov identifier number | **Protocol:** Title page | 7/30/2010 |
| Added second sentence to last paragraph: "Remember, you can change your mind at any time." | **Minor Assent Forms:**<br>Minor Allo Recipient Assent (7 to 11);<br>Minor Auto Recipient Assent (7 to 11);<br>Minor Marrow Toxic Injury Assent (7 to 11) | 7/30/2010 |
| Added the option of "None of the above" to the list of information that may be used to register the recipient's transplant. | **Recipient Consent Forms (Section II):**<br>Adult Auto Recipient;<br>Minor Auto Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Added the paragraph: "The primary purpose of using your child's Social Security Number is to register your child's transplant. An additional use could be to link to other national databases for specific research related to stem cell transplantation." | **Recipient Consent Forms (Section II):**<br>Minor Auto Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Added the paragraph: "The primary purpose of using your Social Security Number is to register your transplant. An additional use could be to link to other national databases for specific research related to stem cell transplantation." | **Recipient Consent Forms (Section II):**<br>Adult Auto Recipient | 7/30/2010 |
| Reworded first paragraph: "If you agree to allow your child to take part in the Research Database, your child's transplant will be registered with the NMDP/CIBMTR. ~~As part of the registration process,~~ <u>In order to avoid duplication, we would like to send</u> your child's Social Security Number, mother's maiden name, and location of birth ~~are sent~~ to the NMDP/CIBMTR. The NMDP/CIBMTR uses these data to make a unique identification number (ID). ~~that is used by your child's transplant center to send your child's medical information to the NMDP/CIBMTR. Using this unique identification number improves the quality of the Database by making sure patients are only registered once in the Database. The information which is used to make your child's unique ID is not kept in the Research Database. It is kept in a separate, secure database.~~ This unique ID number does not contain any identifying information." | **Recipient Consent Forms (Section II):**<br>Minor Auto Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Reworded first paragraph: "If you agree to take part in the | **Recipient Consent Forms** | 7/30/2010 |

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| Research Database, your transplant will be registered with the NMDP/CIBMTR. ~~As part of the registration process,~~ In order to avoid duplication, we would like to send your Social Security Number, mother's maiden name, and location of birth ~~are sent~~ to the NMDP/CIBMTR. The NMDP/CIBMTR uses these data to make a unique identification number (ID). ~~that is used by your transplant center to send your medical information to the NMDP/CIBMTR. Using this unique identification number improves the quality of the Database by making sure patients are only registered once in the Database. The information which is used to make your unique ID is not kept in the Research Database. It is kept in a separate, secure database.~~ This unique ID number does not contain any identifying information." | **(Section II):**<br>Adult Auto Recipient | |
| Reworded last sentence of fourth paragraph as follows: "~~If you agree~~ If your child agrees to participate, and you allow your child to take part in the Research Database, your child's data will be used in research studies." | **Recipient Consent Forms (Section II):**<br>Minor Auto Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Reworded last sentence of first paragraph as follows: "~~If your child takes~~ If your child agrees to participate, and you allow your child to take part in the Research Database, his/her data will be used in research studies." | **Recipient Consent Forms (Section II):**<br>Minor Allo Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Reworded last sentence of first paragraph as follows: "If you agree to take part in the Research Database, your data will be used in research studies." (same change made to 4th paragraph in adult auto consent) | **Recipient Consent Forms (Section II):**<br>Adult Allo Recipient;<br>Adult Auto Recipient | 7/30/2010 |
| Deleted "If your child agrees to participate, and you allow your child to take part in the Research Database" from the beginning of first paragraph. | **Recipient Consent Forms (Section II):**<br>Minor Allo Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Deleted "If you agree to take part in the Research Database" from beginning of first paragraph. | **Recipient Consent Forms (Section II):**<br>Adult Allo Recipient | 7/30/2010 |
| Paragraph 2; added second sentence "If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact NMDP Donor Advocacy at 1-800/526-7809, extension 8710." | **Donor Consent Forms (Section VIII):**<br>Adult Donor | 7/30/2010 |
| Paragraph 2: added second sentence "If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact a Patient Services Coordinator with the NMDP Office of Patient Advocacy at 1-888/999-6743 or patientinfo@nmdp.org." | **Recipient Consent Forms (Section VIII):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient<br>Parent/Legal Guardian;<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury<br>Parent/Legal Guardian | 7/30/2010 |
| Reworded first sentence as follows: "If you have questions, ~~or~~ concerns, or complaints about …" | **Donor Consent Forms (Section VIII):**<br>Adult Donor<br>**Recipient Consent Forms** | 7/30/2010 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| | **(Section VIII):**<br>Adult Allo Recipient;<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Adult Auto Recipient;<br>Minor Auto Recipient<br>Parent/Legal Guardian;<br>Adult Marrow Toxic Injury;<br>Minor Marrow Toxic Injury<br>Parent/Legal Guardian | |
| Reworded end of 2nd paragraph: "When you agree to allow your child to take part in the Research Database, you agree to these audits, ~~You also agree that~~ which may include copying parts of your child's medical record ~~may be copied~~." | **Recipient Consent Forms (Section IV):**<br>Minor Auto Recipient<br>Parent/Legal Guardian;<br>Minor Marrow Toxic Injury<br>Parent/Legal Guardia; | 7/30/2010 |
| Reworded end of 2nd paragraph: "When your child agrees to take part in the Research Database, he/she is agreeing to these audits, which may include copying ~~Your child is also agreeing that~~ parts of his/her medical record ~~may be copied~~." | **Recipient Consent Forms (Section IV):**<br>Minor Allo Recipient<br>Parent/Legal Guardian; | 7/30/2010 |
| Reworded end of 2nd paragraph: "When you agree to take part in the Research Database, you agree to these audits, which may include copying ~~You also agree that~~ parts of your medical record ~~may be copied~~." | **Donor Consent Forms (Section IV):**<br>Adult Donor<br>**Recipient Consent Forms (Section IV):**<br>Adult Allo Recipient;<br>Adult Auto Recipient;<br>Adult Marrow Toxic Injury | 7/30/2010 |
| Deleted the sentence, "Your child's data will only be labeled with a number code." | **Recipient Consent Forms (Section III):**<br>Minor Marrow Toxic Injury<br>Parent/Legal Guardian | 7/30/2010 |
| Deleted the sentences, "Your child's data will only be labeled with a number code. No one will be able to identify your child from this number." | **Recipient Consent Forms (Section III):**<br>Minor Allo Recipient<br>Parent/Legal Guardian;<br>Minor Auto Recipient<br>Parent/Legal Guardian | 7/30/2010 |
| Deleted the sentences, "Your data will only be labeled with a number code. No one will be able to identify you from this number." | **Recipient Consent Forms (Section III):**<br>Adult Allo Recipient;<br>Adult Auto Recipient | 7/30/2010 |
| Deleted the sentence, "Your data will only be labeled with a number code." | **Donor Consent Forms (Section III):**<br>Adult Donor<br>**Recipient Consent Forms (Section III):**<br>Adult Marrow Toxic Injury | 7/30/2010 |
| Changed the address for the Milwaukee campus | **Protocol:** Title page | 7/30/2009 |
| Added the first sentence, "In the event of a radiation exposure accident, the NMDP has a radiation injury…" | **Protocol:** Section 2.2 | 7/30/2009 |
| Changed "Radiation Injury Transplant Network" to "Radiation Injury Treatment Network" | **Protocol:** Section 2.2 | 7/30/2009 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| Added "…and have an IRB Authorization Agreement in place with the NMDP that includes the Research Database protocol." | **Protocol:** Section 3, second paragraph | 7/30/2009 |
| Added "for research purposes" | **Protocol:** Section 3.1, 5th bullet | 7/30/2009 |
| Changed "to the Research Database" to "for research purposes" | **Protocol:** Section 3.1, 6th bullet | 7/30/2009 |
| Added an asterisk after "At the time of product collection" | **Protocol:** Section 4.3 table | 7/30/2009 |
| Added "and donation" | **Protocol:** Section 4.3, last paragraph | 7/30/2009 |
| Changed "August 2004" to "October 2008" | **Protocol:** Section 4.3, last paragraph | 7/30/2009 |
| Added 4th paragraph, "The CIBMTR may engage in studies with other registries where data from subjects in both…" | **Protocol:** Section 5, 4th paragraph | 7/30/2009 |
| Changed "used for research purposes" to "included in data sets for analysis" | **Protocol:** Section 8, 4th paragraph | 7/30/2009 |
| Added line to write in Donor ID # on each page of donor consent form | **Consent Form:** Adult Donor | 7/30/2009 |
| Changed Dr. Douglas Rizzo's phone number to 1-414-805-0700. | **Consent Forms:** Adult Donor; Adult Allo Recipient; Allo Parent/Legal Guardian; Adult Auto Recipient; Auto Parent/Legal Guardian; Adult Marrow Toxic Injury; Parent/Legal Guardian Marrow Toxic Injury | 7/30/2009 |
| Corrected typo: Added the "s" to "data reviews" in Section IV, second paragraph. | **Consent Forms:** Adult Donor; Adult Marrow Toxic Injury; Parent/Legal Guardian Marrow Toxic Injury | 7/30/2009 |
| Section II of the Adult Donor Research Consent Form: The first two paragraphs were combined into one and reworded as follows: "~~If you agree to take part in the Research Database~~, As part of your donation, data about your blood and tissue type, race, gender and age, and infectious disease tests will be sent to the NMDP/CIBMTR. Your cells may be tested to find out the number and types of cells, to make sure that the product is sterile, and to learn other things that may be important to the transplant. Additionally, ~~Y~~you will be contacted after the donation and asked questions to see if you are having pain or other symptoms related to the donation. ~~This information about your recovery will also be sent to the NMDP/CIBMTR.~~ If you agree to take part in the Research Database, ~~your data will be used in research studies.~~ these data that have already been collected will be available to researchers. ~~Additionally, your cells may be tested to find out the number and types of cells, to make sure that the product is sterile, and to learn other things that may be important to the transplant. If you agree to take part in the Research Database, these data may also be used for research purposes~~." | **Consent Form:** Adult Donor | 7/30/2009 |
| Deleted "and Marrow Toxic Injuries" from title of forms that are not for marrow toxic injury patients | **Consent Forms:** Adult Donor; Adult Allo Recipient; Parent/Legal Guardian | 7/30/2008 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| | Allo; Adult Auto Recipient; Parent/Legal Guardian Auto; Minor Allo Assents; Minor Auto Assents | |
| Added that studies must be reviewed by a group of scientists "within NMDP/CIBMTR." | **Consent Forms** Section II | 7/30/2008 |
| Removed mention that studies must be reviewed by the NMDP IRB and replaced it with "NMDP will also review the proposed study…" | **Consent Forms** Section II | 7/30/2008 |
| Removed the sentence "An IRB is a group of people who protect the rights of research participants." | **Consent Forms** Section II | 7/30/2008 |
| Clarified "No identifiable information about you" rather than just "Your name." | **Consent Forms** Section III | 7/30/2008 |
| Capitalized "Research Database" throughout the forms. | **Consent Forms** | 7/30/2008 |
| Changed Suite 500 to 100 in NMDP's address. | Donor Consent Form Section IX | 7/30/2008 |
| Added "transplant-related data" | **Consent Forms** Section II: Adult Allo Recipient; Parent/Legal Guardian Allo Recipient | 7/30/2008 |
| Removed "NMDP" before "Research Database" | **Consent Forms** Section II: Adult Auto Recipient; Parent/Legal Guardian Auto Recipient | 7/30/2008 |
| Changed "study" to "project" | Minor Assent Forms (7-11) | 7/30/2008 |
| Changed "study" to "database" throughout form | Minor Assent Forms (12-17) | 7/30/2008 |
| Removed the sentence "This research study is not about getting a transplant." | Minor Allo Assent Form (12-17); Minor Auto Assent Form (12-17) | 7/30/2008 |
| Removed the sentence "This research study is not about getting treatment." | Minor Marrow Toxic Injury Assent Form (12-17) | 7/30/2008 |
| Revisions to section 2.4 *Informed Consent*, to include mention of assent and refer to parental consent as "permission" | **Protocol:** Section 2.4 | 7/30/2007 |
| Revisions to Minor Assent section to state local IRBs are responsible for determination of method to document minor assent | **Protocol:** Section 2.4.1 | 7/30/2007 |
| Include caveat that minor must be "capable of providing assent" and confirm parent/legal guardian permission is sufficient if minor lacks capacity to provide assent | **Protocol:** Section 2.4.1 | 7/30/2007 |
| Prepared additional parent permission and assent forms for minor Autologous recipients and minor Marrow Toxic Injury patients | New informed consent documents | 7/30/2007 |
| Revised mention of Parent/Legal Guardian "consent" to "permission" in title and section statement section | Legal Guardian Consent Forms | 7/30/2007 |
| Revised description of "Registering your Transplant" to include description for the necessity for registration, and allow for selection of each identifying component separate | Autologous Consent Form | 7/30/2007 |
| Corrected title on all consent forms | **Consent Forms** | 7/30/2007 |
| Added full board name for IRB | **Consent Forms** | 7/30/2007 |
| To avoid repetitive language, revised section III stating the NMDP/CIBMTR will try hard to avoid a loss of confidentiality to read "NMDP/CIBMTR have procedures in place to keep your data private" | **Consent Forms** | 7/30/2007 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

| | | |
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| Replaced use of "quitting" in two instances to "change your mind" and "this" in the withdrawal language | **Consent Forms** | 7/30/2007 |
| New Principal Investigator: J. Douglas Rizzo, M.D., M.S. | **Protocol** | 6/11/2007 |
| Revisions throughout protocol to accurately portray inclusion of related, unrelated and autologous recipients including the following specific revisions:<br>• References to "unrelated" recipients revised to include related, unrelated and autologous translants.<br>• Replaced references to NMDP to read 'NMDP/CIBMTR'<br>• When applicable refer specifically to US centers | **Protocol** | 6/11/2007 |
| Section 1.2 revised to discuss involvement/history of CIBMTR | **Protocol:** Section 1.2 | 6/11/2007 |
| Document that data in Database are observational data – the CIBMTR/NMDP does not determine therapy for participants | **Protocol:** Section 1.3 | 6/11/2007 |
| Marrow Toxic Injury participation revised to state inclusion of individuals at a center participating in the NMDP's Radiation Injury Transplant Network. Additional mention that therapy is at the discretion of care facility, not determined by NMDP/CIBMTR | **Protocol:** Section 2.2 | 6/11/2007 |
| Added "unrelated" to donor eligibility criteria to clearly document database only includes data for *unrelated* donors | **Protocol:** Section 2.3 | 6/11/2007 |
| Added information stating that documentation of consent to participate is included on first submitted form | **Protocol:** Section 2.4 | 6/11/2007 |
| Added information regarding documentation of ethics review for contribution of data from non-US centers | **Protocol:** Section 2.4 | 6/11/2007 |
| Added information documenting that the procedural risk in this protocol meets the definitions in 45 CFR 46.102 | **Protocol:** Section 2.4.1 | 6/11/2007 |
| Removed the option allowing centers to prepare site specific protocol | **Protocol:** Section 3.0 | 6/11/2007 |
| Added language to document international sites must follow the local national regulations | **Protocol:** Section 3.0 | 6/11/2007 |
| Addition of data collected for registration | **Protocol:** Section 4.1, 4.2 | 6/11/2007 |
| Addition of data collection for: pre-existing medical conditions, data collected during filgrastim injection (PBSC donors), complete blood count at annual follow-up, Modified Toxicity Criteria and Health status | **Protocol:** Section 4.2 | 6/11/2007 |
| Added section describing "Collaboration with Other Registries" | **Protocol:** Section 5.0 | 6/11/2007 |
| Revised section to allow for NMDP IRB Chair administrative review for requests for data – use of data not considered "human research" | **Protocol:** Section 6 | 6/11/2007 |
| Include more specific information regarding data analysis | **Protocol:** Section 6 – paragraph 2 | 6/11/2007 |
| Withdrawal language more clearly states that participants can withdraw consent for use of data for "research purposes". | **Protocol:** Section 7 | 6/11/2007 |
| New language included in description of methods in place to maintain confidentiality | **Protocol:** Section 8 – paragraphs 2-4, 6-7 | 6/11/2007 |
| Attachment removed – sites no longer allowed to prepare center specific protocol | **Protocol:** Attachment 1 | 6/11/2007 |
| Added CIBMTR to study invitation and referred to NMDP/CIBMTR throughout consent form | **Consent Forms:** Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor | 6/11/2007 |
| Revised statement regarding NMDP IRB "approval" to | **Consent Forms:** | 6/11/2007 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

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| reflect an administrative review process: "The studies will also be reviewed by the NMDP IRB to make sure the research is consistent with the types of studies described above. An IRB is a group of people who protect the rights of research participants." | Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Marrow Toxic Injury | |
| Revised language in Confidentiality Section to state the NMDP/CIBMTR will not "intentionally" disclose subject's participation and will make every effort to maintain strict confidentiality | **Consent Forms:** Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Marrow Toxic Injury | 6/11/2007 |
| Updated Principal Investigator information | **Consent Forms:** Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Marrow Toxic Injury | 6/11/2007 |
| Revised the Authorization language to more accurately state that if authorization is cancelled data will no longer be used for research purposes | **Consent Forms:** Donor, Marrow Toxic Injury | 6/11/2007 |
| Prepared Autologous Recipient consent form | New Consent Form | 6/11/2007 |
| Revised to include provisions and procedures for incorporating data from individuals exposed to radiation or other chemicals that may result in marrow toxic injury | **Protocol Title** **Protocol:** Sections 1, 2, 3, 4.2, 4.4, 7 | 7/30/2006 |
| Clarified "parent or legal guardian" as the entity responsible for providing permission for minors to participate | **Protocol:** Section 2.3.1 | 7/30/2006 |
| Minor modifications clarifying the NMDP IRB Office's role in the IRB approval process for the Repository | **Protocol:** Section 3.1, 3.2 | 7/30/2006 |
| Revision to state that the CIBMTR will define the policies and procedures for release of data | **Protocol:** Section 5.1 | 7/30/2006 |
| Revised wording regarding risk of identification of participant from "small risk that someone could find out which data is yours" to small risk that an unauthorized person could find out which data is yours" | Recipient Consent Form Section III<br>Legal Guardian Consent Form Section III | 7/30/2006 |
| Added sentence "It is up to you if you want to participate in the Research Database" | Recipient Consent Form Section VI<br>Legal Guardian Consent Form Section VI | 7/30/2006 |
| Corrected voluntary participation and withdrawal language to read "you and your child" | Legal Guardian Consent Form Section VI | 7/30/2006 |
| Removed the phrase "My signature below says that" from the subject's statement of consent | Recipient Consent Form Section X<br>Legal Guardian Consent Form Section X | 7/30/2006 |
| Discontinued use of donor consent combining language regarding participation in Research Repository and Research Database | | 7/30/2006 |
| Prepared separate consent form for donor participation in Research Database | | 7/30/2006 |
| Prepared consent form for participation in Research Database for individuals experiencing marrow toxic injuries | | 7/30/2006 |
| Updated Section 2.2 to reflect the title of the new PBSC study (combining primary and secondary donations) and include full PBSC v Marrow randomized trial study title | **Protocol:** Section 2.2 | 7/30/2005 |
| Replaced Dennis Confer, M.D. with space to provide Donor Center Medical Director contact information | Donor Consent Section VIII | 7/30/2005 |

# RECORD OF REVISIONS:

## *Center for International Blood and Marrow Transplant Research (CIBMTR): Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries* (IRB-2002-0063)

| | | |
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| Replaced Dennis Confer, M.D. with contact information for new PI | Recipient Consent Section VIII | 7/30/2005 |
| Corrected "You do not waive any liability rights for personal injury by signing this form" with "You do not waive any legal rights by signing this form." | Donor Consent Section VIII | 7/30/2005 |
| Identify the NMDP IRB as the group of people who monitor the use the data and protect the participant's rights. | Donor Consent Section II<br>Recipient Consent Section II | 7/30/2005 |
| Changed "Legal Guardian Consent" to "Parental /Legal Guardian Signature" and updated signature lines to "Parent/Legal Guardian" | Minor Assent Form (7 to 11)<br>Minor Assent Form (12 to 17) | 7/30/2005 |
| Prepared Parental/Legal Guardian consent form to be used with the minor assent forms | | 7/30/2005 |
| Attachment 1 updated to include sample language from revised consent forms and the IRB recommendation to include a section to document the attestation of a counseling healthcare professional. | **Protocol**<br>Attachment 1 | 7/30/2004 |
| Protocol amended to include a statement that data from donor product tests (number and types of cells, sterility and other factors) may be used for research purposes. | **Protocol**<br>Section 4.2 *Collection of Donor Data* Paragraph 2 | 7/30/2004 |
| Section added to include Time-Point of "At the time of product collection" and Data Collected to include "Number and type of cells, Sterility, Other factors related to transplant" | **Protocol**, Section 4.2 *Collection of Donor Data*, Time-point/Data Collected chart | 7/30/2004 |
| Consent form re-written at a more appropriate reading level. | Recipient Consent form | 7/30/2004 |
| Consent to participate in the Research Database has been separated from the Consent to Donate. A new consent form has been prepared to combine the donor consent for the Research Database and Research Repository studies into one consent form. | Donor Consent form<br>New consent form | 7/30/2004 |
| The *Consent to Donate form* has been removed from the study. Since the consent to participate in the Research Database has been separated from the donors consent to donate, there are no longer any "research activities" included in the *Consent to Donate* and therefore does not require IRB approval. | Previous *Consent to Donate Form* now replaced with combined consent form to allow donor to consent to the Research Database and Research Repository. | 7/30/2004 |
| Confirmatory Testing consent withdrawn from database study because all data collected during CT is used for strictly anonymous studies | | 10/1/2003 |
| Formatting changes:<br>Organized Research Database Protocol to parallel Research Repository Protocol<br>Added Table of Contents | **Protocol** | 10/1/2003 |
| Section added addressing justification for Minor Consent | **Protocol**: Section 2 | 10/1/2003 |
| Statement addressing tracking of donor consent for bone marrow donation vs donor consent for participation in the Research Database | **Protocol:** Section 2 | 10/1/2003 |
| Number of transplants updated | **Protocol** | 10/1/2003 |
| Section added outlining IRB approval process for centers | **Protocol:** Section 3 | 10/1/2003 |

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| contributing research data | | |
| Attachment added defining minimum requirements set forth by the NMDP IRB for centers writing their own protocols and consent forms | **Protocol:** Attachment 1 | 10/1/2003 |
| Title changed from "*Intent to Donate"* to "*Consent to Donate Bone Marrow and Participation in the NMDP Research Database*" | Consent to Donate | 10/1/2003 |
| Invitation and Purpose section includes invitation for both bone marrow donation and participation in research database | Consent to Donate Section I | 10/1/2003 |
| All mention of "quality of life" data removed and, if applicable, corrected to refer only to ability to return to work, school and leisure activities. | Consent to Donate<br>Sections I, III, V | 10/1/2003 |
| Separate sub-sections added for Donation of Bone Marrow and Research Database | Section I<br>Consent to Donate | 10/1/2003 |
| Studies to determine recovery of donors added to list of potential studies | Protocol Section 1<br>Section I<br>Recipient/Subject Consent<br>Consent to Donate | 10/1/2003 |
| All mention of "quality of life" data removed and, if applicable, corrected to refer only to ability to return to work or school. | Recipient/Subject Consent<br>Sections I, II, III, IV, VII | 10/1/2003 |
| Verbiage added to indicate right to withdraw from participation in the research database | Section VIII<br>Consent to Donate | 10/1/2003 |
| Section added to provide contact information for questions or concerns about rights as research subject | Section XI<br>Consent to Donate | 10/1/2003 |
| "Authorization to Use and Disclose Health Information for Research Purposes" and "Database Consent" sections moved to end of consent form | Section XIII<br>Consent to Donate | 10/1/2003 |
| "No more than 15 mLs (3 teaspoons) of the bone marrow product will be used for these tests" added to section II. | Section II, paragraph 4<br>Consent to Donate | 10/1/2003 |
| Phrase "ethnic" replaced with "racial and ethnic" | Sections II, V<br>Recipient/Subject Consent | 10/1/2003 |
| Language added to indicate proposed studies are reviewed by human subjects protection committee before data is released | Section II<br>Recipient/Subject Consent | 10/1/2003 |
| Minor Assent for ages 7 to 11 approved | | 10/1/2003 |
| Minor Assent for ages 12 to 17 approved | | 10/1/2003 |