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 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
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):** Adult Donor **Recipient Consent Forms (Section I, paragraph 2):** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section I, paragraph 2):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	07/30/2016
Paragraph 1, 1st sentence: "~~If you agree to take part in the~~	**Recipient Consent Forms**	07/30/2016

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~~Research Database, y~~Your transplant or cellular therapy will be registered with the CIBMTR."	**(Section II):** Adult Autologous Recipient; Minor Autologous Recipient Parent/Legal Guardian	
Paragraph 2: Updated NMDP's address	**Donor Consent Forms (Section IX):** Adult Donor	07/30/2016
Added 2nd sentence: "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."	**Protocol:** Section 2.4	07/30/2015
Branding changes were applied to all consent and assent forms to remove references to NMDP (i.e., ~~NMDP/~~CIBMTR).	**Donor Consent Forms:** Adult Donor **Recipient Consent Forms:** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms:** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian **Assent Forms:** Minor Allo Assent 7-11; Minor Allo Assent 12-17; Minor Auto Assent 7-11; Minor Auto Assent 12-17; Minor Marrow Toxic Injury Assent 7-11; Minor Marrow Toxic Injury Assent 12-17	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 you to take part in a Research Database."	**Donor Consent Forms (Section I):** Adult Donor **Recipient Consent Forms (Section I):** Adult Allogeneic Recipient; Adult Autologous Recipient **Marrow Toxic Injury Consent Forms (Section I):** 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):** Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient	07/30/2014

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	Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section I):** Minor Marrow Toxic Injury Parent/Legal Guardian	
Paragraph 1: "…will be available to researchers <u>through the CIBMTR.</u>"	**Donor Consent Forms (Section II):** Adult Donor	07/30/2014
"…all research studies using these data must first be approved by a group of scientists within <u>the</u> ~~NMDP/~~CIBMTR. ~~NMDP~~ <u>The proposed study</u> will also <u>be</u> review<u>ed</u> ~~the proposed study~~ to make sure the research is consistent with the types of studies described above."	**Donor Consent Forms (Section II):** Adult Donor **Recipient Consent Forms (Section II):** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section II):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	07/30/2014
"<u>Your donor center and</u> the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Donor Consent Forms (Section IV):** Adult Donor	07/30/2014
"<u>Your treatment center and</u> the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Recipient Consent Forms (Section IV):** Adult Allogeneic Recipient; Adult Autologous Recipient **Marrow Toxic Injury Consent Forms (Section IV):** Adult Marrow Toxic Injury	07/30/2014
"<u>Your child's treatment center and</u> the ~~NMDP/~~CIBMTR ~~has~~ have procedures in place…"	**Recipient Consent Forms (Section IV):** Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section IV):** Minor Marrow Toxic Injury Parent/Legal Guardian	07/30/2014
"Web site" was changed to one word "website".	**Donor Consent Forms (Section IV):** Adult Donor **Recipient Consent Forms (Section IV):** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient	07/30/2014

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	Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section IV):** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	
"~~NMDP~~ Be The Match Donor Advocacy"	**Donor Consent Forms (Section VIII):** Adult Donor	07/30/2014
Paragraph 2: References to "NMDP" were changed to "Be The Match".	**Donor Consent Forms (Section IX):** 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):** Adult Allogeneic Recipient; Adult Autologous Recipient	07/30/2014
Paragraph 2: "Due to the need to follow-up with you after your child's transplant or cellular therapy, please tell your ~~transplant~~ treatment center if your contact information changes."	**Recipient Consent Forms (Section VIII):** Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian	07/30/2014
Paragraph 2: "…with Be the Match® Patient and Health Professional Services…"	**Recipient Consent Forms (Section IX):** Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian **Marrow Toxic Injury Consent Forms (Section VIII):** Adult Marrow Toxic Injury; 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 or other registries outside the NMDP/CIBMTR…"	**Recipient Consent Forms (Section II):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient (paragraph 4); Minor Auto Recipient Parent/Legal Guardian (paragraph 4);	07/30/2013

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New Section VIII with the following wording: PERMISSION TO CONTACT FOR FUTURE CIBMTR RESEARCH STUDIES 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. 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. ☐ I AGREE to allow CIBMTR to contact me about future studies. ☐ I DO NOT want CIBMTR to contact me about future studies.	**Recipient Consent Forms (Section VIII):** Adult Allo Recipient; Adult Auto Recipient	07/30/2013
New Section VIII with the following wording: PERMISSION TO CONTACT FOR FUTURE CIBMTR RESEARCH STUDIES 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. 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. ☐ I AGREE to allow CIBMTR to contact me about future studies for which my child is eligible.	**Recipient Consent Forms (Section VIII):** Minor Allo Recipient Parent/Legal Guardian; Minor Auto Recipient Parent/Legal Guardian	07/30/2013

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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: • How well recipients recover from their transplants or cellular therapy; • How recovery after transplantation or cellular therapy can be improved; • Long-term outcomes after transplantation or cellular therapy, • 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." Paragraph 2, 1st sentence: "…transplants and other cellular therapies work well." Paragraph 2, 2nd sentence: "…had a transplant or other cellular therapy." Paragraph 3, 1st sentence: "…your transplant or cellular therapy will be registered…" Paragraph 4, 1st sentence: "…about your transplant or cellular therapy and how you do after the transplant or cellular therapy and send it…" Paragraph 4, 3rd sentence: "…ways to make transplants and other cellular therapies work better." 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

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." Paragraph 2, 1st sentence: "…transplants and other cellular therapies work well." Paragraph 2, 2nd sentence: "…had a transplant or other cellular therapy." Paragraph 3, 1st sentence: "…about your transplant or cellular therapy and how you do after the transplant or cellular therapy and send it…" Paragraph 3, 3rd sentence: "…ways to make transplants and cellular therapies work better." Paragraph 3, last sentence: "You will have a transplant or cellular therapy for your disease…" Paragraph 4, last sentence: "…how to make transplants and other cellular therapies work better in the future."	**Minor Assent Forms:** Minor Allo Recipient Assent (12 to 17);	7/30/2012
Paragraph 1, 2nd sentence: "…transplants and cellular therapies work." Paragraph 2, 1st sentence: "…transplant or cellular therapy goes." Paragraph 2, 2nd sentence: "…your transplant or cellular therapy." Paragraph 2, last sentence: "…transplant or cellular therapy anyway." Paragraph 3, last sentence: "…need a transplant or cellular therapy." Paragraph 4, 1st sentence: "…your transplant or cellular therapy."	**Minor Assent Forms:** Minor Allo Recipient Assent (7 to 11); Minor Auto Recipient Assent (7 to 11)	7/30/2012
Paragraph 1: "…(~~Transplant~~ Treatment Center Physician)…"	**Recipient Consent Forms (Section VIII):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; 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):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/2012
Sentence 2: "…~~planned treatment~~ transplant or cellular therapy, but…"	**Recipient Consent Forms (Section VII):** 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):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient;	
Paragraph 2, last sentence: "…~~hospital or clinic~~ <u>treatment center</u>…"	**Recipient Consent Forms (Section VI):** Minor Auto Recipient Parent/Legal Guardian;	7/30/2012
Paragraph 2, last sentence: "…~~transplant~~ <u>treatment</u> center…"	**Recipient Consent Forms (Section VI):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient;	7/30/2012
Paragraph 1, 1st sentence: "…~~transplant~~ <u>treatment</u> center…" Paragraph 2, 1st sentence: "…~~transplant~~ <u>treatment</u> center…"	**Recipient Consent Forms (Section IV):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian;	7/30/2012
Paragraph 2, 2nd sentence: "…~~transplant~~ <u>treatment</u> center…"	**Recipient Consent Forms (Section III):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian;	7/30/2012
Paragraph 2, 1st sentence: "…transplant <u>or cellular therapy</u>." Paragraph 3: "…transplant <u>or cellular therapy</u> with the…" Paragraph 4, 1st sentence: "…~~transplant~~ <u>treatment</u> center will send…" Paragraph 4, 1st sentence: "…transplant <u>or cellular therapy</u> to the NMDP/CIBMTR." Paragraph 4, 2nd sentence: "…transplant <u>or cellular therapy</u>, and once a year…"	**Recipient Consent Forms (Section II):** Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian;	7/30/2012
Paragraph 2, 1st sentence: "...transplant-related <u>or cellular therapy-related</u> data may be shared…"	**Recipient Consent Forms (Section II):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian;	7/30/2012
Paragraph 1, 2nd sentence: "…transplant <u>or cellular therapy</u>, and once a year…"	**Recipient Consent Forms (Section II):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian;	7/30/2012
Paragraph 1, 1st sentence: "…transplant <u>or cellular therapy</u> will be…"	**Recipient Consent Forms (Section II):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient	7/30/2012

	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):** Adult Donor **Recipient Consent Forms (Section IV):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; Adult Marrow Toxic Injury; 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):** Adult Donor **Recipient Consent Forms (Section IV):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; Adult Marrow Toxic Injury; 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):** Adult Donor **Recipient Consent Forms (Section III):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; 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):** Adult Donor	7/30/2012
Paragraph 2, 1st sentence: "…transplants and other cellular therapies work well."	**Recipient Consent Forms (Section I):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; 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

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Sentence 3: "…transplants and other cellular therapies work better." Bullet 1: "…from their transplant or cellular therapy;" Bullet 2: "…after a transplant or cellular therapy can be…" Bullet 3: "…to transplant or cellular therapy for different."	Adult Donor **Recipient Consent Forms (Section I):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; 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:** Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian **Minor Assent Forms:** Minor Marrow Toxic Injury Assent (7 to 11); 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:** Adult Donor **Recipient Consent Forms:** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; **Minor Assent Forms:** Minor Allo Recipient Assent (7 to 11); Minor Allo Recipient Assent (12 to 17); Minor Auto Recipient Assent (7 to 11); 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

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 2.2: Individuals with Marrow Toxic Injury Eligibility Criteria 2.3: Unrelated Donor Eligibility Criteria 4.3: Collection of Unrelated Donor Data 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:** 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:** 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:** Minor Allo Recipient Assent (12 to 17); 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):** 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):** Adult Donor **Recipient Consent Forms (Section IV):** Adult Allo Recipient; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; Adult Marrow Toxic Injury; 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):** Minor Allo Recipient	7/30/2011

meetings."	Parent/Legal Guardian; Minor Auto Recipient Parent/Legal Guardian; Minor Marrow Toxic Injury 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):** Adult Donor **Recipient Consent Forms (Section III):** Adult Allo Recipient; Adult Auto Recipient; 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:** Minor Allo Recipient Assent (7 to 11); Minor Auto Recipient Assent (7 to 11); 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):** Adult Auto Recipient; Minor Auto Recipient 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):** Minor Auto Recipient 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):** 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):** Minor Auto Recipient 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):** 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):** Minor Auto Recipient 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):** Minor Allo Recipient 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):** Adult Allo Recipient; 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):** Minor Allo Recipient 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):** 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):** 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):** Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; Adult Marrow Toxic Injury; Minor Marrow Toxic Injury 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):** Adult Donor **Recipient Consent Forms**	7/30/2010

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	(Section VIII): Adult Allo Recipient; Minor Allo Recipient Parent/Legal Guardian; Adult Auto Recipient; Minor Auto Recipient Parent/Legal Guardian; Adult Marrow Toxic Injury; Minor Marrow Toxic Injury 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~~ <u>which may include copying</u> parts of your child's medical record ~~may be copied~~."	**Recipient Consent Forms (Section IV):** Minor Auto Recipient Parent/Legal Guardian; Minor Marrow Toxic Injury 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, <u>which may include copying</u> ~~Your child is also agreeing that~~ parts of his/her medical record ~~may be copied~~."	**Recipient Consent Forms (Section IV):** Minor Allo Recipient 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, <u>which may include copying</u> ~~You also agree that~~ parts of your medical record ~~may be copied~~."	**Donor Consent Forms (Section IV):** Adult Donor **Recipient Consent Forms (Section IV):** Adult Allo Recipient; Adult Auto Recipient; 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):** Minor Marrow Toxic Injury 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):** Minor Allo Recipient Parent/Legal Guardian; Minor Auto Recipient 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):** Adult Allo Recipient; Adult Auto Recipient	7/30/2010
Deleted the sentence, "Your data will only be labeled with a number code."	**Donor Consent Forms (Section III):** Adult Donor **Recipient Consent Forms (Section III):** 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

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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

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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

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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: • References to "unrelated" recipients revised to include related, unrelated and autologous translants. • Replaced references to NMDP to read 'NMDP/CIBMTR' • 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

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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 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 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 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

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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 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) 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** 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** 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 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: Organized Research Database Protocol to parallel Research Repository Protocol 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

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 Sections I, III, V	10/1/2003
Separate sub-sections added for Donation of Bone Marrow and Research Database	Section I Consent to Donate	10/1/2003
Studies to determine recovery of donors added to list of potential studies	Protocol Section 1 Section I Recipient/Subject Consent 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 Sections I, II, III, IV, VII	10/1/2003
Verbiage added to indicate right to withdraw from participation in the research database	Section VIII Consent to Donate	10/1/2003
Section added to provide contact information for questions or concerns about rights as research subject	Section XI 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 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 Consent to Donate	10/1/2003
Phrase "ethnic" replaced with "racial and ethnic"	Sections II, V 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 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