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

Added additional language to clarify what happens if the participant joins the study.		
Section 1: Added statement about being able to partake in the CMS study without participating in the Research Database.	Adult CMS Studies Consent Form	12/6/2021
Removed Statement: "your healthcare costs are covered by Medicare" Added: "you have healthcare insurance coverage from Medicare"		
Removed: "The goal of this research is to see how well BMT works to treat your disease"		
Section 2: Clarified that data may be used in future research studies related to Medicare coverage of participants disease.		
Section 3: Added language to clarify coverage subject to copays, deductibles, and other fees.		
Section 4: Removed: NCT Identifier Number		
Added: "Centers for Medicare and Medicaid Services (CMS)" to the list of groups that may access participant's medical records		
Removed statement about CIBMTR selling data to third parties from CMS consent;		
Section 5: 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: 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 Adult Allogenic Recipient Adult Autologous Recipient; Adult Marrow Toxic Injury; Adult CMS Studies	12/6/2021
Minor grammatical and formatting updates throughout consent forms to eliminate redundancies and improve clarity.	Adult Donor Consent Form Adult Allogenic Recipient Adult Autologous Recipient; Adult Marrow Toxic Injury; 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 Adult Allogenic Recipient Adult Autologous Recipient; Adult Marrow Toxic Injury; Adult CMS Studies	12/6/2021
Section 10: Added clarifying language on how CIBMTR	Protocol: Section 10	12/6/2021

securely stores and handles patient data.		
Section 9: Edited language to better describe the collection	Protocol: Section 9	12/6/2021
and use of Patient Contact Information.		
Section 4.3:	Protocol: Section 4.3	12/6/2021
Replaced "filgrastim injections" with broader "mobilization		
agent administration".		
Removed Annual timepoint from Post HC collection		
schedule.		
Section 4: Added administrative claims data as a source of	Protocol Section: 4	12/6/2021
data collection and added language to clarify that the exact		
data being collected may evolve with changes in standard		
practice.		
Section 1.4: Added language to identify data collected under	Protocol Section: 1.4	12/6/2021
the protocol may be used in combination with specimens	Totocol Section: 1.4	12/0/2021
collected by the CIBMTR protocol for Research Sample		
Repository Section 1: Renumbered and reformatted subsections 1.1	Protocol: Section 1	12/6/2021
	Protocol: Section 1	12/0/2021
through 1.4 for numerical flow.	A 11	07/00/2020
Updated language to reduce language level and increase	All consent forms	07/09/2020
subject understanding		
Section 4: Confidentiality and Use of Information language	Adult Donor Consent Form	07/09/2020
expanded	Adult Allogeneic Recipient;	
	Adult Autologous Recipient;	
	Adult Marrow Toxic Injury;	
	Adult CMS Studies	
Section 5: Cost and Reimbursement language expanded	Adult Donor Consent Form	07/09/2020
	Adult Allogeneic Recipient;	
	Adult Autologous Recipient;	
	Adult Marrow Toxic Injury;	
	Adult CMS Studies	
1. Overall edited to reduce redundancies and create	Protocol: throughout the entire	07/30/2019
better flow of information in the protocol.	protocol.	
2. Removed references to data being collected on		
forms as data may be collected by other modes.		
3. Substituted the generic "patient" to describe all		
individuals who received a HC transplant, cellular		
therapy or treatment for marrow toxic injury.		
4. "Recipient" was only used when "patient" would		
not make sense in the context of the sentence.		
5. Substituted the "participant" for "patient and donor"		
when referring to both.		
6. Substituted "treatment center" for "transplant		
center."		
7. Substituted "healthcare record" for "medical		
record."		
8. Deleted all references to regenerative medicine and		
used the more generic "cellular therapy."		
ased the more generic contrar therapy.		
Broke Section 1.2 into two distinct sections $-1.2$ for Medical	Protocol: Section 1	07/30/2019
College of Wisconsin and 1.3 for CIBMTR		07/30/2017
Conege of wisconsin and 1.5 for CIDIVITK		

Added a statement to clarify that participants only need to	Protocol: Section 2.4	07/30/2019
sign one consent form even if they are receiving multiple	Protocol: Section 2.4	07/30/2019
subsequent treatment that covered under this protocol.		
Added that centers can delegate review of the protocol to the	Protocol: Section 3	07/30/2019
	FIOLOCOL Section 5	07/30/2019
NMDP IRB through an IRB Authorization Agreement.		
Added that protocol and consent forms can be found on the CIBMTR website.		
	Protocol: Section 3.1	07/30/2019
Updated to include process for 2018 Common Rule	Protocol: Section 5.1	07/30/2019
Requirements.	Protocol: Section 4.3	07/30/2019
Added product data collection.		
Added section on patient reported outcomes.	Protocol: Section 4.5	07/30/2019
Administrative IRB approval for using patient identifiers	Protocol: Section 5	07/30/2019
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 6	07/30/2019
Last paragraph of section rewritten at a higher level with	Protocol: Section 6	07/30/2019
examples of types of collaboration and types of data that may		
be exchanged. Section 7.2 was broken into two distinct sections – 7.2 How	Drate cell Section 7.2 and 7.2	07/20/2010
	Protocol: Section 7.2 and 7.3	07/30/2019
Requests are Reviewed/Approved and 7.3 for How Data Sets		
are Prepared and Shared		
Responsibility for ensuring that research studies using data	Protocol: Section 7.2	07/30/2019
from Research Database fall within the scope of the protocol		0110012019
and consent from was switched from an administrative		
review by the IRB chair to the CIBMTR Observational		
Research group.		
Statement was added about what happens to a patient's data	Protocol: Section 8	07/30/2019
when he/she withdraws from the protocol.		
The patient's preferred language was added to the contact	Protocol: Section 9	07/30/2019
information that is collected if a patient agrees to provide		
contact information to the CIBMTR.		
Statement was added that studies that require direct contact	Protocol: Section 9	07/30/2019
with the patient by CIBMTR will be conducted under the		
CIBMTR protocol Research Database Protocol for Patient		
Reported Outcomes.		
Added that donors will also be assigned a Global Registry	Protocol: Section 10	07/30/2019
Identifier for Donors (GRID) when they join the NMDP		
Registry. The GRID will be used to track donor information		
in the Research Database.		
Changed title of consent form: Adult Unrelated Donor	Unrelated Donor Consent Form:	07/30/2019
Research Consent Form		
Section 2, beginning of second paragraph added:	Unrelated Donor Consent Form:	07/30/2019
Your donation-related data may be shared with researchers,		2.700,2017
collaborating organizations, or other registries outside the		
CIBMTR. The data that is shared will not include any		
<u>CIBMTR.</u> The data that is shared will not include any information that could identify you. Section 3, second to last sentence in paragraph added:	Unrelated Donor Consent Form:	07/30/2019
	Unrelated Donor Consent Form:	07/30/2019

Unarlated Demon Concernt Former	07/20/2010
Unrelated Donor Consent Form:	07/30/2019
	05/20/2010
	07/30/2019
Guardian Consent Form	
CMS Studies Adult/Parent Legal	07/30/2019
Guardian Consent Form	
CMS Studies Adult/Parent Legal	07/30/2019
Guardian Consent Form	
CMS Studies Adult/Parent Legal	07/30/2019
Guardian Consent Form	
CMS Studies Minor Assent Ages	07/30/2019
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Marrow Toxic Injury	07/30/2019
Marrow Toxic Injury Adult/Parent Legal Guardian	07/30/2019
	07/30/2019
Adult/Parent Legal Guardian	07/30/2019
Adult/Parent Legal Guardian	07/30/2019
Adult/Parent Legal Guardian	07/30/2019
Adult/Parent Legal Guardian Consent Form	
	Guardian Consent Form CMS Studies Adult/Parent Legal Guardian Consent Form

Section 5 added: Your data may be used for commercial projects and profit. If your data is used for commercial projects, you will not share	Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form	07/30/2019
in any profit. Section 8: Added to first paragraph: ( <i>Treatment Center Physician</i> ) ( <i>telephone number</i> ). Added to second paragraph: ( <i>Enter Transplant Center office</i>	Marrow Toxic Injury Adult/Parent Legal Guardian Consent Form	07/30/2019
of research subject advocacy contact information). Just under title: *Adult Allogeneic Recipient Research Consent Form and Parent/Legal Guardian Permission Form Allogeneic Recipient	Recipient Allo Adult/Parent Legal Guardian Consent Form	07/30/2019
Added: <u>The word "you" throughout this form refers to you or your</u> <u>child.</u> * Adult consent form and parent/legal guardian permission		
form were combined into one document Section 2, first paragraph, 2nd sentence: These medical data may include medical records <del>claims</del> data such as the billing codes for procedures <u>diagnosis or</u> <u>procedure codes</u> , and tests or health care services that your treatment center <del>submits to insurance companies for payment</del> <u>provides</u> .	Recipient Allo Adult/Parent Legal Guardian Consent Form	07/30/2019
Section 2, second paragraph, first sentence: 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: 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: 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: By checking the "AGREE" box below, you are only agreeing to give the CIBMTR your contact information <u>and preferred</u> <u>language</u> , so that the CIBMTR can contact you to tell you about the study.	Recipient Allo Adult/Parent Legal Guardian Consent Form	07/30/2019
Added a line for Preferred Language		

Section 9, first paragraph, first sentence: Dr. Douglass Rizzo, <u>Senior</u> Associate Scientific Director	Recipient Allo Adult/Parent Legal Guardian Consent Form	07/30/2019
Section 9, second paragraph, first sentence: please contact <del>Roberta King</del> , <u>the</u> NMDP IRB Administrator	Recipient Allo Adult/Parent Legal Guardian Consent Form	07/30/2019
Second sentence: please contact Patient Service Coordinator <u>BMT Patient</u> <u>Navigator</u> with Be The Match Patient <del>and Health</del> <del>Professional</del> Services at 1-888-999-6743 or <u>patientinfo@nmdp.org</u> or (Enter Transplant Center office of <u>research subject advocacy contact information</u> ).		
Section 10 Recipient/Subject Signature ( <i>if 18 years or older</i> )	Recipient Allo Adult/Parent Legal Guardian Consent Form	07/30/2019
Added lines for printed name and signature of parent/legal guardian		
Just under title: *Adult Autologous Recipient Research Consent Form and Parent/Legal Guardian Permission Form Autologous Recipient Added:	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019
The word "you" throughout this form refers to you or your child.		
* Adult consent form and parent/legal guardian permission form were combined into one document		
Section 2, fourth paragraph, second sentence: These medical data may include medical records <del>claims</del> data such as the billing codes for procedures <u>diagnosis or</u> <u>procedure codes</u> , and tests or health care services that your treatment center <del>submits to insurance companies for payment</del> <u>provides</u> .	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019
Section 2, fourth paragraph, first sentence: 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: 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: <u>Your data may be used for commercial projects and profit. If</u> your data is used for commercial projects, you will not share	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019

<u>in any profit.</u>		
Section 8, first paragraph, last sentence: By checking the "AGREE" box below, you are only agreeing to give the CIBMTR your contact information <u>and preferred</u> <u>language</u> , so that the CIBMTR can contact you to tell you about the study.	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019
Added a line for Preferred Language		
Section 6, first paragraph, last sentence: 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: Dr. Douglass Rizzo, <u>Senior</u> Associate Scientific Director	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019
Section 9, second paragraph, first sentence: please contact <del>Roberta King</del> , <u>the</u> NMDP IRB Administrator	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019
Second sentence: please contact Patient Service Coordinator BMT Patient <u>Navigator</u> 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).		
Section 10 Recipient/Subject Signature <u>(<i>if 18 years or older</i>)</u> Added lines for printed name and signature of parent/legal	Recipient Auto Adult/Parent Legal Guardian Consent Form	07/30/2019
guardian Underneath the title:	Recipient Minor Assent Form (7 -	07/30/2019
Minor Allogeneic Recipient Assent Form (7 to 11 years of age) Allogeneic or Autologous Recipient	11)	07/30/2017
<u>* Minor allo/auto assent forms for ages 7 - 11 were</u> combined into one document		
Underneath the title: Minor Allogeneic Recipient Assent Form (12 to 17 years of age) Allogeneic or Autologous Recipient	Recipient Minor Assent Form (12 - 17)	07/30/2019
* Minor allo/auto assent forms for ages 12 - 17 were combined into one document		
Deleted the paragraph: 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

Added 3 <sup>rd</sup> bullet point: " <u>Determine how a donor's or</u> recipient's genetics impact recipient recovery after a	Donor Consent Form (Section I):	07/30/2018
1 <sup>st</sup> paragraph, added 2 <sup>nd</sup> sentence: " <u>These medical data may</u> 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."	Recipient Consent Forms (Section II): Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian Adult Autologous Recipient; Minor Autologous Recipient Parent/Legal Guardian (Section II, 4 <sup>th</sup> paragraph, 2 <sup>nd</sup> sentence)	07/30/2018
registries"	Minor Allogeneic Recipient Parent/Legal Guardian Adult Autologous Recipient; Minor Autologous Recipient Parent/Legal Guardian (Section II, 5 <sup>th</sup> paragraph, 1 <sup>st</sup> sentence)	
2 <sup>nd</sup> paragraph, 1 <sup>st</sup> sentence: "Your transplant-related or cellular therapy-related data may be shared with investigators, <u>collaborating organizations</u> , or other	Recipient Consent Forms (Section II): Adult Allogeneic Recipient;	07/30/2018
1 <sup>st</sup> paragraph, last sentence: "By checking the 'AGREE' box below, you are only agreeing <u>to give the CIBMTR your</u> <u>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
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
GRID line added to footer of consent form.	<b>Donor Consent Form (footer):</b> Adult Donor Unrelated	05/15/2019
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.		

transplant or cellular therapy."	Adult Donor	
tunsplant of contrar therapy:		
	Recipient Consent Forms (Section I): Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian	
1 <sup>st</sup> paragraph: "The Center for International Blood and Marrow Transplant Research (CIBMTR), <del>the</del> <u>a</u> research <del>program</del> <u>collaboration</u> of the National Marrow Donor program (NMDP)/Be The Match <u>and the Medical College of</u> <u>Wisconsin</u> ."	Donor Consent Form (Section I): Adult Donor Recipient Consent Forms (Section I): Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient Parent/Legal Guardian; Minor Autologous Recipient Parent/Legal Guardian	07/30/2018
	Marrow Toxic Injury Consent Forms (Section I): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian CMS Studies Consent Form (Section I): Adult CMS Studies	
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 6 <sup>th</sup> paragraph: " <u>The Research Database protocol is</u> <u>covered by a National Institutes of Health Certificate of</u> <u>Confidentiality (CoC). The CoC protects identifiable</u> <u>research information from forced disclosure in any civil,</u> <u>criminal, administrative, legislative, or other proceeding,</u> <u>whether at the federal, state, or local level.</u> "	Protocol: Section 10	07/30/2018
4 <sup>th</sup> paragraph: "the unique identification number is	<b>Protocol</b> : Section 10	07/30/2018

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
1 <sup>st</sup> paragraph: "Once the study has been approved, the	<b>Protocol</b> : Section 7.2	07/30/2018
NMDP and the MCW IRB are is informed of new studies"		
Added entire Section 6. Collaborations with Other	<b>Protocol</b> : Section 6	07/30/2018
Organizations		01/10/2010
"In no cases would the recipient, individual with a marrow	<b>Protocol</b> : Section 4.4	07/30/2018
toxic injury or donor be contacted in order to obtain	Trotocol. Section 4.4	07/30/2018
additional data <u>without IRB approval for the specific study</u>		
and IRB-approved consent from the participant for the		
specific study."		05/20/2010
Last paragraph: "unless the donor gives consent to	<b>Protocol</b> : Section 4.3	07/30/2018
participate in the Research Database at <u>either</u> the time he/she		
joins the Registry or is requested to donate for a recipient."		
1 <sup>st</sup> paragraph: "Transplant <u>Treatment</u> Center staff"	<b>Protocol</b> : Section 4.3	07/30/2018
1 <sup>st</sup> paragraph: "Transplant <u>Treatment</u> Centers complete the	<b>Protocol</b> : Section 4.2	07/30/2018
forms at the following time-points."		
Added to data collected annually starting year three:	<b>Protocol</b> : Table in Section 4.1	07/30/2018
"Quality of life"		
Added to data collected at 100 days, six months, one year,	<b>Protocol</b> : Table in Section 4.1	07/30/2018
two year, post-transplant or cellular therapy:		
" <u>Quality of life</u> "		
"100 days, six months, one year, two year, post-transplant <u>or</u>	<b>Protocol</b> : Table in Section 4.1	07/30/2018
<u>cellular therapy</u> "		0110012010
Added to data collected at the time of transplant or cellular	<b>Protocol</b> : Table in Section 4.1	07/30/2018
therapy:	Trotocon. Table in Section 4.1	07/30/2010
"Pre-transplant or cellular therapy disease-specific data such		
as blood counts, disease status, cytogenetics"		
"Co-existing disease at the time of transplant <u>or cellular</u>		
therapy"		
"HSC or cellular therapy product manipulation"		
"Quality of life"		
"At the time of transplant or cellular therapy"	<b>Protocol</b> : Table in Section 4.1	07/30/2018
Added to data collected at registration: "If patient provides	<b>Protocol</b> : Table in Section 4.1	07/30/2018
written consent to collect contact information, the following		
will also be collected: Address, Phone numbers, Email		
address"		
1 <sup>st</sup> paragraph: "Recipient data are collected from pre-	<b>Protocol</b> : Section 4.1	07/30/2018
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."		
1 <sup>st</sup> paragraph: "All U.S. centers must have an IRB-approved	<b>Protocol</b> : Section 3	07/30/2018
protocol and consent forms prior to submitting data about		
transplant <u>or cellular therapy</u> recipients, <del>transplant</del> donors, or		
individuals with marrow toxic injury"		
	1	

(A 11 1	Protocol, Section 2.2	07/20/2019
"All donors registered on the NMDP Registry, regardless of	<b>Protocol</b> : Section 2.3	07/30/2018
whether they who have been requested to donate a		
product"		
5 <sup>th</sup> bullet point; 4 <sup>th</sup> paragraph: "How access to	<b>Protocol</b> : Section 1.3	07/30/2018
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"		
Added 4 <sup>th</sup> bullet point; 4 <sup>th</sup> paragraph: " <u>Molecular</u>	<b>Protocol</b> : Section 1.3	07/30/2018
explanations for histocompatibility or clinical outcome		07/30/2010
revealed through analysis of genomic, epigenetic, or other		
biomolecular data"		
		07/20/2010
4 <sup>th</sup> paragraph: "The <del>primary</del> purpose of the Research	<b>Protocol</b> : Section 1.3	07/30/2018
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 <u>or marrow toxic injuries</u> ."	Protocol Continu 1.2	07/20/2010
2 <sup>nd</sup> paragraph: "Secondary More recent goals of the	<b>Protocol</b> : Section 1.3	07/30/2018
CIBMTR Research program"		
1st paragraph: "The primary original goal of the CIBMTR	<b>Protocol</b> : Section 1.3	07/30/2018
Research Program"		
1 <sup>st</sup> paragraph: "The CIBMTR is an <u>research</u> affiliation	<b>Protocol:</b> Section 1.2	07/30/2018
between the NMDP and the Medical College of Wisconsin."		
Added Section 6 Collaborating with other Organizations and	<b>Protocol:</b> Page 2 Table of	07/30/2018
Section 9 Participant Contact Information to Table of	Contents	
Contents		
Protocol version date and number changed to July 2018,	<b>Protocol:</b> Title page	07/30/2018
Version 8.0.	Trotocol. The page	07/30/2010
	Donor Concert Form (Section	01/22/2019
Paragraph 1, last sentence: "If you agree to take part in the	Donor Consent Form (Section	01/23/2018
Research Database, these data that have already been	II):	
collected will be available to researchers through the	Adult Donor	
CIBMTR used in research studies."		
After paragraph 3: "This research is covered by a Certificate	<b>Recipient Consent Forms</b>	01/23/2018
of Confidentiality from the National Institutes of Health. The	(Section IV):	
researchers with this Certificate may not disclose or use	Minor Allogeneic Recipient	
information, documents, or biospecimens that may identify	Parent/Legal Guardian;	
your child in any federal, state, or local civil, criminal,	Minor Autologous Recipient	
administrative, legislative, or other action, suit, or	Parent/Legal Guardian	
proceeding, or be used as evidence, for example, if there is a		
court subpoena, unless you have consented for this use.	Marrow Toxic Injury Consent	
Information, documents, or biospecimens protected by this	Forms (Section IV):	
Certificate cannot be disclosed to anyone else who is not	Minor Marrow Toxic Injury	
connected with the research except, if there is a federal, state,	Parent/Legal Guardian	

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.		
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.		
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	<b>Recipient Consent Forms</b>	01/23/2018
Certificate of Confidentiality from the National Institutes of	(Section IV):	
Health. The researchers with this Certificate may not disclose	Adult Allogeneic Recipient;	
or use information, documents, or biospecimens that may	Adult Autologous Recipient;	
identify you in any federal, state, or local civil, criminal,	See reepiere,	
administrative, legislative, or other action, suit, or	Marrow Toxic Injury Consent	
proceeding, or be used as evidence, for example, if there is a	Forms (Section IV):	
court subpoena, unless you have consented for this use.	Adult Marrow Toxic Injury;	
Information, documents, or biospecimens protected by this	real march rone figury,	
Certificate cannot be disclosed to anyone else who is not	CMS Studies Consent Form	
connected with the research except, if there is a federal, state,	(Section IV):	
or local law that requires disclosure (such as to report child	Adult CMS Studies	
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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.       Donor Consent Form (Section IV): Adult Donor         The Certificate cannot be used to refuse a request for information from program evaluation by Health Resources and Services Administration (HRAA or National Institutes of Health (NH) which is funding this project that is needed for auditing or program evaluation by Health Resources and Services Administration (HRAA). You should understand that a Certificate of Confidentiality does not prevent voa Iforn volumarily 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.         To expand research, it is helpful for researchers to share information the research, but be able to see and the desaes. If you agree to take part in the Research Database, some of your health information release, some of your health information from other studies. Researchers outside the CIBMTR, Researchers and other Information from abus tudius, but your runame and other information from the rutifies and on your transplant or cellular therapy that is collected prior to your transplant or cellular therapy"       Recipient Consent Form (Section II): Adult Autologous Recipient therapy"         Paragraph 4: "Your child's treatment center will send medical data about your clickes and after your child's discurs will send medical data about your child's discurs will send medical data about your child's discurs will send medical data about your child's discurs will send medicaid data about your child's discurs will sen			1
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Paragraph 3: "If you take part in the Research Database,	Assent Form:	07/30/2017
$\frac{\mathbf{y}}{\mathbf{Y}}$ our transplant or cellular therapy will be registered with the CIBMTR."	Minor Auto Assent 12-17	
Added a new consent form titled: Prospective Assessment of	New Consent Form	02/08/2017
Allogeneic Hematopoietic Cell Transplantation in Patients		
with Medicare Coverage		
Added Section 6.3 Studies Designed to Inform U.S.	<b>Protocol:</b> Section 6.3	02/08/2017
Medicare Policy		
Added to 4 <sup>th</sup> bullet point: How access to transplantation or	Protocol: Section 1.3	02/08/2017
cellular therapy for different groups of patients can be		
improved, including studies designed to inform		
insurance/government payer policy, such as U.S. Medicare		
policy;		
Changed NMDP's address	Protocol: Title page	07/30/2016
Paragraph 1: Deleted last sentence, "Annually, more than	<b>Protocol:</b> Section 1.1	07/30/2016
5,000 patients initiate an active donor search through the		
NMDP, and over 3,000 of these searches result in		
transplants."		
Paragraph 1: "Although the exact studies for which	Donor Consent Forms (Section	07/30/2016
Research Database data may be used is are not known at this	I):	
time"	Adult Donor	
	<b>Recipient Consent Forms</b>	
	(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	
Paragraph 1, 1 <sup>st</sup> sentence: "If you agree to take part in the	<b>Recipient Consent Forms</b>	07/30/2016
Research Database, yYour transplant or cellular therapy will	(Section II):	
be registered with the CIBMTR."	Adult Autologous Recipient;	
	Minor Autologous Recipient	
	Parent/Legal Guardian	
Paragraph 2: Updated NMDP's address	<b>Donor Consent Forms (Section</b>	07/30/2016
	IX):	
	Adult Donor	
Added 2 <sup>nd</sup> sentence: "Whenever possible, patients should be	<b>Protocol:</b> Section 2.4	07/30/2015
informed about the protocol and asked to provide consent to		07/30/2013
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 accurred "		
patient's consent after the transplant has occurred."	Donor Consent Forms:	07/30/2014
Branding changes were applied to all consent and assent forms to remove references to NMDP (i.e.,		07/30/2014
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Minor Autologous 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 12-17; Minor Allo Assent 12-17; Minor Auto Assent 12-17; Minor Auto Assent 12-17; Minor Auto Assent 12-17; Minor Auto Assent 12-17; 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)/Re The Match, invites you to take part in a Research Database."       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)/Re The Match, invites your child to take part in a Research Database."       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)/Re The Match, invites your child to take part in a Research Database."       07/30/2014         Paragraph 1: ", will be available to researchers through the Queroved by a group of scientists within the approved by a group o			
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Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient	review <u>ed</u> the proposed study to make sure the research is	<b>Recipient Consent Forms</b>	
Adult Allogeneic Recipient; Adult Autologous Recipient; Minor Allogeneic Recipient	consistent with the types of studies described above."		
Adult Autologous Recipient; Minor Allogeneic Recipient		Adult Allogeneic Recipient;	
Minor Allogeneic Recipient			

	Minor Autologous Recipient	
	Parent/Legal Guardian	
	Marrow Toxic Injury Consent	
	Forms (Section II):	
	Adult Marrow Toxic Injury;	
	Minor Marrow Toxic Injury	
	Parent/Legal Guardian	
"Your donor center and the NMDP/CIBMTR has have	<b>Donor Consent Forms (Section</b>	07/30/2014
procedures in place"	<b>IV</b> ):	
	Adult Donor	
"Your treatment center and the NMDP/CIBMTR has have	Recipient Consent Forms	07/30/2014
procedures in place"	(Section IV):	
	Adult Allogeneic Recipient;	
	Adult Autologous Recipient	
	Marrow Toxic Injury Consent	
	Forms (Section IV):	
	Adult Marrow Toxic Injury	
"Your child's treatment center and the NMDP/CIBMTR has	Recipient Consent Forms	07/30/2014
have procedures in place"	(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	
"Web site" was changed to one word "website".	Donor Consent Forms (Section	07/30/2014
website was changed to one word website .	IV):	07/30/2014
	Adult Donor	
	Recipient Consent Forms	
	(Section IV):	
	Adult Allogeneic Recipient;	
	Adult Autologous Recipient;	
	Minor Allogeneic Recipient	
	Parent/Legal Guardian;	
	Minor Autologous Recipient	
	Parent/Legal Guardian	
	Parent/Legal Guardian Marrow Toxic Injury Consent	
	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV):	
	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury;	
	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury	
	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	
" <del>NMDP</del> <u>Be The Match</u> Donor Advocacy"	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section	07/30/2014
"NMDP Be The Match Donor Advocacy"	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII):	07/30/2014
	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII): Adult Donor	
Paragraph 2: References to "NMDP" were changed to "Be	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII):	07/30/2014
	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII): Adult Donor Donor Consent Forms (Section IX):	
Paragraph 2: References to "NMDP" were changed to "Be	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII): Adult Donor Donor Consent Forms (Section	
Paragraph 2: References to "NMDP" were changed to "Be The Match". Paragraph 2: "Due to the need to follow-up with you after	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII): Adult Donor Donor Consent Forms (Section IX):	
Paragraph 2: References to "NMDP" were changed to "Be The Match".	Parent/Legal Guardian Marrow Toxic Injury Consent Forms (Section IV): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section VIII): Adult Donor Donor Consent Forms (Section IX): Adult Donor	07/30/2014

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

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

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

Dave small 5 last containers " how to make the market and	1	
Paragraph 5, last sentence: "how to make transplants <u>and</u>		
other cellular therapies work better in the future."		7/20/2012
Paragraph 1, last sentence: "transplant, <u>or cellular</u>	Minor Assent Forms:	7/30/2012
therapy."	Minor Allo Recipient Assent (12	
Paragraph 2, 1 <sup>st</sup> sentence: "transplants <u>and other cellular</u>	to 17);	
therapies work well."		
Paragraph 2, 2 <sup>nd</sup> sentence: "had a transplant or other		
cellular therapy."		
Paragraph 3, 1 <sup>st</sup> sentence: "about your transplant or		
<u>cellular therapy</u> and how you do after the transplant <u>or</u>		
cellular therapy and send it"		
Paragraph 3, 3 <sup>rd</sup> sentence: "ways to make transplants <u>and</u>		
cellular therapies work better."		
Paragraph 3, last sentence: "You will have a transplant or		
<u>cellular therapy</u> for your disease"		
Paragraph 4, last sentence: "how to make transplants and		
other cellular therapies work better in the future."		
Paragraph 1, 2 <sup>nd</sup> sentence: "transplants and cellular	Minor Assent Forms:	7/30/2012
therapies work."	Minor Allo Recipient Assent (7 to	
Paragraph 2, 1 <sup>st</sup> sentence: "transplant <u>or cellular therapy</u>	11);	
goes."	Minor Auto Recipient Assent (7	
Paragraph 2, 2 <sup>nd</sup> sentence: "your transplant or cellular	to 11)	
therapy."		
Paragraph 2, last sentence: "transplant or cellular therapy		
anyway."		
Paragraph 3, last sentence: "need a transplant or cellular		
therapy."		
Paragraph 4, 1 <sup>st</sup> sentence: "your transplant or cellular		
therapy."		
Paragraph 1: "(Transplant Treatment Center	Recipient Consent Forms	7/30/2012
Physician)"	(Section VIII):	
	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
Paragraph 2, 2 <sup>nd</sup> sentence: "Patient Services Coordinator	Recipient Consent Forms	7/30/2012
with the NMDP Office of Patient Advocacy Be the Match <sup>®</sup>	(Section VIII):	//30/2012
Patient Services at"	Adult Allo Recipient;	
<u>radent Services</u> at	Minor Allo Recipient	
	1	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
	Adult Marrow Toxic Injury;	
	Minor Marrow Toxic Injury	
	Parent/Legal Guardian	<b>R</b> 100 100 1 7
Sentence 2: "planned treatment transplant or cellular	<b>Recipient Consent Forms</b>	7/30/2012
therapy, but"	(Section VII):	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
Sentence 2: "transplant or cellular therapy as	<b>Recipient Consent Forms</b>	7/30/2012

scheduled"	(Section VII):	
scheduled	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
Paragraph 2, last sentence: "hospital or clinic treatment	Recipient Consent Forms	7/30/2012
center"	(Section VI):	7/30/2012
	Minor Auto Recipient	
	Parent/Legal Guardian;	
Paragraph 2, last sentence: "transplant treatment	Recipient Consent Forms	7/30/2012
center"	(Section VI):	7/30/2012
	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
Paragraph 1, 1 <sup>st</sup> sentence: "transplant treatment center"	Recipient Consent Forms	7/30/2012
Paragraph 2, 1 <sup>st</sup> sentence: "transplant <u>treatment</u> center"	(Section IV):	1150/2012
rangraph 2, 1 sononooamisphant <u>arounnoni</u> contor	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
Paragraph 2, 2 <sup>nd</sup> sentence: "transplant treatment center"	Recipient Consent Forms	7/30/2012
r dragraph 2, 2 sentencetransplant <u>dreatment</u> center	(Section III):	7750/2012
	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
Paragraph 2, 1 <sup>st</sup> sentence: "transplant or cellular therapy."	Recipient Consent Forms	7/30/2012
Paragraph 3: "transplant <u>or cellular therapy</u> with the"	(Section II):	
Paragraph 4, 1 <sup>st</sup> sentence: "transplant treatment center will	Adult Auto Recipient;	
send"	Minor Auto Recipient	
Paragraph 4, 1 <sup>st</sup> sentence: "transplant or cellular therapy	Parent/Legal Guardian;	
to the NMDP/CIBMTR."	e ,	
Paragraph 4, 2 <sup>nd</sup> sentence: "transplant or cellular therapy,		
and once a year"		
Paragraph 2, 1 <sup>st</sup> sentence: "transplant-related or cellular	Recipient Consent Forms	7/30/2012
therapy-related data may be shared"	(Section II):	
	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
Paragraph 1, 2 <sup>nd</sup> sentence: "transplant or cellular therapy,	<b>Recipient Consent Forms</b>	7/30/2012
and once a year"	(Section II):	
	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
Paragraph 1, 1 <sup>st</sup> sentence: "transplant or cellular therapy	<b>Recipient Consent Forms</b>	7/30/2012
will be"	(Section II):	
	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
	Minor Auto Recipient	

	Parent/Legal Guardian;	
Added Paragraph 3: "A description of this clinical study will	Donor Consent Form (Section	7/30/2012
be available on http://www.ClinicalTrials.gov, as required by	IV):	
U.S. Law. This Web site will not include information that	Adult Donor	
can identify you. At most, the Web site will include a	<b>Recipient Consent Forms</b>	
summary of the results. You can search this Web site at any	(Section IV):	
time. (Identifier: NCT01166009)"	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	
Paragraph 1, last sentence: "The NMDP/CIBMTR will try	<b>Donor Consent Form (Section</b>	7/30/2012
hard to make sure has procedures in place so that no one	<b>IV</b> ):	
outside the NMDP/CIBMTR will know"	Adult Donor	
	<b>Recipient Consent Forms</b>	
	(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	7/20/2012
Paragraph 3, last sentence: "who need a transplant <u>or</u>	Donor Consent Form (Section	7/30/2012
cellular therapy."	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;	
Paragraph 1, 2 <sup>nd</sup> sentence: "important to the transplant or	Donor Consent Form (Section	7/30/2012
cellular therapy."	II):	1150/2012
<u>condiar anorapy</u> .	Adult Donor	
Paragraph 2, 1 <sup>st</sup> sentence: "transplants and other cellular	Recipient Consent Forms	7/30/2012
therapies work well."	(Section I):	110012012
<u></u>	Adult Allo Recipient;	
	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
Sentence 2: "patients who have had a transplant or other	Donor Consent Form (Section	7/30/2012
<u>cellular therapy</u> and donors who donate"	I):	

Sentence 3: "transplants and other cellular therapies work	Adult Donor	
better."	Recipient Consent Forms	
Bullet 1: "from their transplant or cellular therapy;"	(Section I):	
Bullet 2: "after a transplant or cellular therapy can be"	Adult Allo Recipient;	
Bullet 3: "to transplant or cellular therapy for different."	Minor Allo Recipient	
	Parent/Legal Guardian;	
	Adult Auto Recipient;	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
Consent Form Title: "Research Database for Hematopoietic	Recipient Consent Forms:	7/30/2012
Stem Cell Transplantation, Other Cellular Therapies and	Adult Marrow Toxic Injury;	110012012
Marrow Toxic Injuries"	Minor Marrow Toxic Injury	
inurow rome injuries	Parent/Legal Guardian	
	Minor Assent Forms:	
	Minor Marrow Toxic Injury	
	Assent (7 to 11);	
	Minor Marrow Toxic Injury	
	•••	
	Assent (12 to 17)	7/20/2012
Consent Form Title: "Research Database for Hematopoietic	Donor Consent Form:	7/30/2012
Stem Cell Transplantation and Cellular Therapies"	Adult Donor	
	<b>Recipient Consent Forms:</b>	
	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);	
Paragraph 4, 1 <sup>st</sup> sentence: "Recipients of Ttransplant	Protocol: Section 8	7/30/2012
recipients or hematopoietic cells for regenerative medicine or		1100/2012
immune-based therapy, including for malignancy or		
<u>infection</u> , and individuals with marrow toxic injury"		
Deleted paragraph 2: "All maternal cord blood donors are	<b>Protocol:</b> Section 2.3	7/30/2012
enrolled in the NMDP Cord Blood Bank Investigational New	Frotocol: Section 2.5	7/30/2012
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."		7/20/2012
Sentence 1: "transplant (includes cells collected from	Protocol: Section 2.1	7/30/2012
peripheral blood, bone marrow or cord blood) in a CIBMTR		
center"		
Paragraph 4: Added last bullet "The application and success	Protocol: Section 1.3	7/30/2012
of hematopoietic cells for regenerative medicine or immune-		

application of hematopoietic cells for regenerative medicine		
or immune-based therapy, including for malignancy or		
infection."		
Paragraph 2, 1 <sup>st</sup> sentence: <u>A sSecondary goals</u> of the	<b>Protocol:</b> Section 1.3	7/30/2012
CIBMTR Research Program <u>are to understand uses of</u>	Trotocon. Section 1.5	775072012
hematopoietic cells for regenerative medicine or immune-		
based therapy, including for malignancy or infection, and is		
to improve treatments"		
Paragraph 2: Added last sentence, "In 2011 CIBMTR	<b>Protocol:</b> Section 1.2	7/30/2012
activities were expanded to include uses of hematopoietic	Trotocol. Section 1.2	7/30/2012
<u>cells for regenerative medicine or immune-based therapy</u> ,		
including for malignancy or infection."		
"(HSC)"	<b>Protocol:</b> throughout	7/20/2012
	Protocol: throughout	7/30/2012
"hematopoietic <del>stem</del> cell"	Protocol: throughout	7/30/2012
2.1: Recipient and Marrow Toxic Injury Eligibility Criteria	<b>Protocol:</b> Page 2 Table of	7/30/2012
2.2: Individuals with Marrow Toxic Injury <u>Eligibility</u>	Contents	
Criteria		
2.3: <u>Unrelated</u> Donor Eligibility Criteria		
4.3: Collection of <u>Unrelated</u> Donor Data		
5: Exchange of Data Collaboration with Other Registries		7/20/2012
Title change: Protocol for a Research Database for	Protocol: Title page	7/30/2012
Hematopoietic Stem Cell Transplantation, Other Cellular		
Therapies and Marrow Toxic Injuries		
Paragraph 1: Last sentence "You are being asked to	Minor Assent Forms:	7/30/2011
participate in this database because <u>you</u> have been"	Minor Marrow Toxic Injury	
	Assent (12 to 17)	
Paragraph 6: 2 <sup>nd</sup> sentence "Your doctors or your parents	Minor Assent Forms:	7/30/2011
cannot will not make you be in"	Minor Auto Recipient Assent (12	
D 1 7 and (TT 1	to 17)	E /20 /2011
Paragraph 5: 2 <sup>nd</sup> sentence "Your doctors or your parents	Minor Assent Forms:	7/30/2011
cannot will not make you be in"	Minor Allo Recipient Assent (12	
	to 17);	
	Minor Marrow Toxic Injury	
	Assent (12 to 17)	7/20/2011
Paragraph 2: Last sentence "he/she is agreeing to these	Recipient Consent Forms	7/30/2011
audits reviews, which may include copying	(Section IV):	
	Minor Allo Recipient	
	Parent/Legal Guardian	7/20/2011
Paragraph 2: Last sentence "you agree to these audits	<b>Donor Consent Form (Section</b>	7/30/2011
<u>reviews</u> , which may include copying	IV):	
	Adult Donor	
	<b>Recipient Consent Forms</b>	
	(Section IV):	
	Adult Allo Recipient;	
	Adult Auto Recipient;	
	Minor Auto Recipient	
	Parent/Legal Guardian;	
	Adult Marrow Toxic Injury;	
	Minor Marrow Toxic Injury	
Demarcanh 2: Added wording to last contance "No	Parent/Legal Guardian	7/20/2011
Paragraph 2: Added wording to last sentence "No	Recipient Consent Forms	7/30/2011
identifiable information about your child will be given to the	(Section III): Minor Allo Paginiant	
researchers, nor will it be published or presented at scientific	Minor Allo Recipient	

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	<b>Donor Consent Form (Section</b>	7/30/2011
identifiable information about you will be given to the	III):	
researchers, nor will it be published or presented at scientific	Adult Donor	
meetings."	Recipient Consent Forms	
	(Section III):	
	Adult Allo Recipient;	
	Adult Auto Recipient;	
	Adult Marrow Toxic Injury;	
Added ClinicalTrials.gov identifier number	<b>Protocol:</b> Title page	7/30/2010
Added second sentence to last paragraph: "Remember, you	Minor Assent Forms:	7/30/2010
can change your mind at any time."	Minor Allo Recipient Assent (7	
	to 11);	
	Minor Auto Recipient Assent (7	
	to 11);	
	Minor Marrow Toxic Injury	
	Assent (7 to 11)	
Added the option of "None of the above" to the list of	Recipient Consent Forms	7/30/2010
information that may be used to register the recipient's	(Section II):	
transplant.	Adult Auto Recipient;	
1	Minor Auto Recipient	
	Parent/Legal Guardian	
Added the paragraph: "The primary purpose of using your	Recipient Consent Forms	7/30/2010
child's Social Security Number is to register your child's	(Section II):	
transplant. An additional use could be to link to other	Minor Auto Recipient	
national databases for specific research related to stem cell	Parent/Legal Guardian	
transplantation."		
Added the paragraph: "The primary purpose of using your	Recipient Consent Forms	7/30/2010
Social Security Number is to register your transplant. An	(Section II):	
additional use could be to link to other national databases for	Adult Auto Recipient	
specific research related to stem cell transplantation."		
Reworded first paragraph: "If you agree to allow your child	<b>Recipient Consent Forms</b>	7/30/2010
to take part in the Research Database, your child's transplant	(Section II):	
will be registered with the NMDP/CIBMTR. As part of the	Minor Auto Recipient	
registration process, In order to avoid duplication, we would	Parent/Legal Guardian	
like to send your child's Social Security Number, mother's	- a chi Dogar Guardian	
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		
$\mathbf{r}_{\mathbf{r}}$		
does not contain any identifying information." Reworded first paragraph: "If you agree to take part in the	Recipient Consent Forms	7/30/2010

Adult Auto Recipient	
Recipient Consent Forms	7/30/2010
	110012010
<u> </u>	7/30/2010
	7/30/2010
<u> </u>	E /20 /2010
	7/30/2010
	7/30/2010
Minor Allo Recipient	
Parent/Legal Guardian	
Recipient Consent Forms	7/30/2010
Section II):	
Adult Allo Recipient	
	7/30/2010
VIII):	
Recipient Consent Forms	7/30/2010
	7/30/2010
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A dult Momenty Terrie Iniumu	
Minor Marrow Toxic Injury	
Minor Marrow Toxic Injury Parent/Legal Guardian	
Minor Marrow Toxic Injury	7/30/2010
Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/2010
Minor Marrow Toxic Injury Parent/Legal Guardian Donor Consent Forms (Section	7/30/2010
	Recipient Consent Forms Section II): Adult Allo Recipient Donor Consent Forms (Section

	(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 2 <sup>nd</sup> paragraph: "When you agree to allow	Recipient Consent Forms	7/30/2010
		//30/2010
your child to take part in the Research Database, you agree to	(Section IV):	
these audits, You also agree that which may include copying	Minor Auto Recipient	
parts of your child's medical record may be copied."	Parent/Legal Guardian;	
	Minor Marrow Toxic Injury	
	Parent/Legal Guardia;	
Reworded end of 2 <sup>nd</sup> paragraph: "When your child agrees to	Recipient Consent Forms	7/30/2010
take part in the Research Database, he/she is agreeing to	(Section IV):	
these audits, which may include copying Your child is also	Minor Allo Recipient	
agreeing that parts of his/her medical record may be copied."	Parent/Legal Guardian;	
Reworded end of 2 <sup>nd</sup> paragraph: "When you agree to take	<b>Donor Consent Forms (Section</b>	7/30/2010
part in the Research Database, you agree to these audits,	<b>IV</b> ):	
which may include copying You also agree that parts of your	Adult Donor	
medical record may be copied."	Recipient Consent Forms	
inculcal record may be copied.	(Section IV):	
	, , ,	
	Adult Allo Recipient;	
	Adult Auto Recipient;	
	Adult Marrow Toxic Injury	
Deleted the sentence, "Your child's data will only be labeled	<b>Recipient Consent Forms</b>	7/30/2010
with a number code."	(Section III):	
	Minor Marrow Toxic Injury	
	Parent/Legal Guardian	
Deleted the sentences, "Your child's data will only be	Recipient Consent Forms	7/30/2010
labeled with a number code. No one will be able to identify	(Section III):	
your child from this number."	Minor Allo Recipient	
y a la l	Parent/Legal Guardian;	
	Minor Auto Recipient	
	Parent/Legal Guardian	
Deleted the sentences, "Your data will only be labeled with a	Recipient Consent Forms	7/30/2010
		//30/2010
number code. No one will be able to identify you from this	(Section III):	
number."	Adult Allo Recipient;	
	Adult Auto Recipient	
Deleted the sentence, "Your data will only be labeled with a	<b>Donor Consent Forms (Section</b>	7/30/2010
number code."	III):	
	Adult Donor	
	<b>Recipient Consent Forms</b>	
	(Section III):	
	Adult Marrow Toxic Injury	
Changed the address for the Milwaukee campus	<b>Protocol:</b> Title page	7/30/2009
Added the first sentence, "In the event of a radiation	Protocol: Section 2.2	7/30/2009
exposure accident, the NMDP has a radiation injury"		1150/2007
	<b>Protocol:</b> Section 2.2	7/30/2009
	LIOUDCOL: SECHOILZ.Z	17.50/2009
Changed "Radiation Injury Transplant Network" to "Radiation Injury Treatment Network"		

Added " and have an IRB Authorization Agreement in	Protocol: Section 3, second	7/30/2009
place with the NMDP that includes the Research Database protocol."	paragraph	
Added "for research purposes"	<b>Protocol:</b> Section 3.1, 5 <sup>th</sup> bullet	7/30/2009
Changed "to the Research Database" to "for research	<b>Protocol:</b> Section 3.1, 6 <sup>th</sup> bullet	7/30/2009
purposes"		
Added an asterisk after "At the time of product collection"	Protocol: Section 4.3 table	7/30/2009
Added "and donation"	<b>Protocol:</b> Section 4.3, last	7/30/2009
C1	paragraph	7/20/2000
Changed "August 2004" to "October 2008"	<b>Protocol:</b> Section 4.3, last paragraph	7/30/2009
Added 4 <sup>th</sup> paragraph, "The CIBMTR may engage in studies	<b>Protocol:</b> Section 5, 4 <sup>th</sup>	7/30/2009
with other registries where data from subjects in both"	paragraph	112012003
Changed "used for research purposes" to "included in data	<b>Protocol:</b> Section 8, 4 <sup>th</sup>	7/30/2009
sets for analysis"	paragraph	
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-	Consent Forms:	7/30/2009
0700.	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	
Corrected typo: Added the "s" to "data reviews" in Section	Consent Forms:	7/30/2009
IV, second paragraph.	Adult Donor; Adult Marrow	
	Toxic Injury; Parent/Legal	
	Guardian Marrow Toxic Injury	
Section II of the Adult Donor Research Consent Form: The	Consent Form:	7/30/2009
first two paragraphs were combined into one and reworded	Adult Donor	
as follows: "If you agree to take part in the Research		
Database, <u>As part of your donation</u> , data about your blood and tissue type, race, gender and age, and infectious disease		
tests will be sent to the NMDP/CIBMTR. <u>Your cells may be</u>		
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, Yyou 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."		
Deleted "and Marrow Toxic Injuries" from title of forms that	Consent Forms:	7/30/2008
are not for marrow toxic injury patients	Adult Donor; Adult Allo	
	Recipient; Parent/Legal Guardian	

	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	Consent Forms Section II	7/30/2008
"within NMDP/CIBMTR."		
Removed mention that studies must be reviewed by the	Consent Forms Section II	7/30/2008
NMDP IRB and replaced it with "NMDP will also review		
the proposed study"		
Removed the sentence "An IRB is a group of people who	Consent Forms Section II	7/30/2008
protect the rights of research participants."		
Clarified "No identifiable information about you" rather than	Consent Forms Section III	7/30/2008
just "Your name." Capitalized "Research Database" throughout the forms.	Consent Forms	7/30/2008
	Donor Consent Form Section IX	
Changed Suite 500 to 100 in NMDP's address.	Consent Forms Section II:	7/30/2008 7/30/2008
Added "transplant-related data"		//30/2008
	Adult Allo Recipient;	
	Parent/Legal Guardian Allo	
Removed "NMDP" before "Research Database"	Recipient Consent Forms Section II:	7/30/2008
Removed NMDP before Research Database	Adult Auto Recipient;	//30/2008
	Parent/Legal Guardian Auto	
	Recipient	
Changed "study" to "project"	Minor Assent Forms (7-11)	7/30/2008
Changed 'study' to project Changed "study" to "database" throughout form	Minor Assent Forms (12-17)	7/30/2008
Removed the sentence "This research study is not about	Minor Allo Assent Form (12-17);	7/30/2008
getting a transplant."	Minor Auto Assent Form (12-17), Minor Auto Assent Form (12-17)	1/30/2000
Removed the sentence "This research study is not about	Minor Marrow Toxic Injury	7/30/2008
getting treatment."	Assent Form (12-17)	1130/2000
Revisions to section 2.4 <i>Informed Consent</i> , to include	Protocol: Section 2.4	7/30/2007
mention of assent and refer to parental consent as		1130/2007
"permission"		
Revisions to Minor Assent section to state local IRBs are	<b>Protocol:</b> Section 2.4.1	7/30/2007
responsible for determination of method to document minor		
assent		
Include caveat that minor must be "capable of providing	Protocol: Section 2.4.1	7/30/2007
assent" and confirm parent/legal guardian permission is		
sufficient if minor lacks capacity to provide assent		
Prepared additional parent permission and assent forms for	New informed consent documents	7/30/2007
minor Autologous recipients and minor Marrow Toxic Injury		
patients		
Revised mention of Parent/Legal Guardian "consent" to	Legal Guardian Consent Forms	7/30/2007
"permission" in title and section statement section		
Revised description of "Registering your Transplant" to	Autologous Consent Form	7/30/2007
include description for the necessity for registration, and		
allow for selection of each identifying component separate		
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	Consent Forms	7/30/2007
NMDP/CIBMTR will try hard to avoid a loss of		
confidentiality to read "NMDP/CIBMTR have procedures in		
place to keep your data private"		

Replaced use of "quitting" in two instances to "change your	Consent Forms	7/30/2007
mind" and "this" in the withdrawal language	Ductorel	c/11/2007
New Principal Investigator: J. Douglas Rizzo, M.D., M.S.	Protocol Protocol	6/11/2007 6/11/2007
Revisions throughout protocol to accurately portray inclusion of related, unrelated and autologous recipients including the	Protocol	0/11/2007
following specific revisions:		
<ul> <li>References to "unrelated" recipients revised to include</li> </ul>		
• References to unrelated recipients revised to include related, unrelated and autologous translants.		
<ul> <li>Replaced references to NMDP to read 'NMDP/CIBMTR'</li> </ul>		
<ul> <li>When applicable refer specifically to US centers</li> </ul>		
Section 1.2 revised to discuss involvement/history of	<b>Protocol:</b> Section 1.2	6/11/2007
CIBMTR	Trotocol. Section 1.2	0/11/2007
Document that data in Database are observational data – the	<b>Protocol:</b> Section 1.3	6/11/2007
CIBMTR/NMDP does not determine therapy for participants	Totocol. Section 1.5	0/11/2007
Marrow Toxic Injury participation revised to state inclusion	Protocol: Section 2.2	6/11/2007
of individuals at a center participating in the NMDP's	Troubeon Section 2.2	0/11/2007
Radiation Injury Transplant Network. Additional mention		
that therapy is at the discretion of care facility, not		
determined by NMDP/CIBMTR		
Added "unrelated" to donor eligibility criteria to clearly	Protocol: Section 2.3	6/11/2007
document database only includes data for <i>unrelated</i> donors		
Added information stating that documentation of consent to	Protocol: Section 2.4	6/11/2007
participate is included on first submitted form		
Added information regarding documentation of ethics review	Protocol: Section 2.4	6/11/2007
for contribution of data from non-US centers		
Added information documenting that the procedural risk in	Protocol: Section 2.4.1	6/11/2007
this protocol meets the definitions in 45 CFR 46.102		
Removed the option allowing centers to prepare site specific	Protocol: Section 3.0	6/11/2007
protocol		C/11/2007
Added language to document international sites must follow	Protocol: Section 3.0	6/11/2007
the local national regulations	Protocol: Section 4.1.4.2	6/11/2007
Addition of data collected for registration Addition of data collection for: pre-existing medical	Protocol: Section 4.1, 4.2 Protocol: Section 4.2	6/11/2007
conditions, data collected during filgrastim injection (PBSC	FIOLOCOL: Section 4.2	0/11/2007
donors), complete blood count at annual follow-up, Modified		
Toxicity Criteria and Health status		
Added section describing "Collaboration with Other	<b>Protocol:</b> Section 5.0	6/11/2007
Registries"	Totocon Section 5.0	0/11/2007
Revised section to allow for NMDP IRB Chair	<b>Protocol:</b> Section 6	6/11/2007
administrative review for requests for data – use of data not		
considered "human research"		
Include more specific information regarding data analysis	<b>Protocol:</b> Section 6 – paragraph 2	6/11/2007
Withdrawal language more clearly states that participants can	Protocol: Section 7	6/11/2007
withdraw consent for use of data for "research purposes".		
New language included in description of methods in place to	<b>Protocol:</b> Section 8 – paragraphs	6/11/2007
maintain confidentiality	2-4, 6-7	
Attachment removed - sites no longer allowed to prepare	Protocol: Attachment 1	6/11/2007
center specific protocol		
Added CIBMTR to study invitation and referred to	Consent Forms:	6/11/2007
NMDP/CIBMTR throughout consent form	Recipient, Legal Guardian/Parent,	
	Minor Assent Forms, Donor	
Revised statement regarding NMDP IRB "approval" to	Consent Forms:	6/11/2007

reflect an administrative review process: "The studies will	Recipient, Legal Guardian/Parent,	
also be reviewed by the NMDP IRB to make sure the	Minor Assent Forms, Donor,	
research is consistent with the types of studies described	Marrow Toxic Injury	
above. An IRB is a group of people who protect the rights of		
research participants."	C (F	6/11/2007
Revised language in Confidentiality Section to state the	Consent Forms:	6/11/2007
NMDP/CIBMTR will not "intentionally" disclose subject's	Recipient, Legal Guardian/Parent,	
participation and will make every effort to maintain strict	Minor Assent Forms, Donor,	
confidentiality	Marrow Toxic Injury	C 11 1 10007
Updated Principal Investigator information	Consent Forms:	6/11/2007
	Recipient, Legal Guardian/Parent,	
	Minor Assent Forms, Donor,	
	Marrow Toxic Injury	C/11/2007
Revised the Authorization language to more accurately state	Consent Forms:	6/11/2007
that if authorization is cancelled data will no longer be used	Donor, Marrow Toxic Injury	
for research purposes	N. C. (E	6/11/2007
Prepared Autologous Recipient consent form	New Consent Form	6/11/2007
Revised to include provisions and procedures for	Protocol Title	7/30/2006
incorporating data from individuals exposed to radiation or	<b>Protocol:</b> Sections 1, 2, 3, 4.2,	
other chemicals that may result in marrow toxic injury	4.4, 7	7/20/2006
Clarified "parent <u>or legal guardian</u> " as the entity responsible	Protocol: Section 2.3.1	7/30/2006
for providing permission for minors to participate		
Minor modifications clarifying the NMDP IRB Office's role	Protocol: Section 3.1, 3.2	7/30/2006
in the IRB approval process for the Repository		
Revision to state that the CIBMTR will define the policies	Protocol: Section 5.1	7/30/2006
and procedures for release of data		E 120 1200 4
Revised wording regarding risk of identification of	Recipient Consent Form Section	7/30/2006
participant from "small risk that someone could find out		
which data is yours" to small risk that <u>an unauthorized</u>	Legal Guardian Consent Form	
person could find out which data is yours"	Section III	7/20/2006
Added sentence "It is up to you if you want to participate in	Recipient Consent Form Section	7/30/2006
the Research Database"	VI L	
	Legal Guardian Consent Form	
	Section VI	7/20/2006
Corrected voluntary participation and withdrawal language to	Legal Guardian Consent Form	7/30/2006
read " <u>you and your child</u> "	Section VI	7/20/2006
Removed the phrase "My signature below says that" from	Recipient Consent Form Section	7/30/2006
the subject's statement of consent	X Legal Cuardian Consent Form	
	Legal Guardian Consent Form	
Discontinued use of demonstration to the large	Section X	7/20/2002
Discontinued use of donor consent combining language		7/30/2006
regarding participation in Research Repository and Research Database		
Prepared separate consent form for donor participation in		7/20/2006
		7/30/2006
Research Database		7/20/2007
Prepared consent form for participation in Research Database		7/30/2006
for individuals experiencing marrow toxic injuries		7/20/2005
Updated Section 2.2 to reflect the title of the new PBSC	Protocol: Section 2.2	7/30/2005
study (combining primary and secondary donations) and		
include full PBSC v Marrow randomized trial study title		<b>E 100 1000 E</b>
Replaced Dennis Confer, M.D. with space to provide Donor	Donor Consent Section VIII	7/30/2005
Center Medical Director contact information		

new PIDescriptionCorrected "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 VIII7/30/2005Identify the NMDP IRB as the group of people who monitor the use the data and protect the participant's rights.Donor Consent Section II7/30/2005Changed "Legal Guardian Consent" to "Parental /LegalMinor Assent Form (7 to 11)7/30/2005	Replaced Dennis Confer, M.D. with contact information for	Recipient Consent Section VIII	7/30/2005
injury by signing this form." With "You do not waive any legal rights by signing this form."         7/30/2005           legal rights by signing this form."         Donor Consent Section II         7/30/2005           Recipient Consent Section II         7/30/2005         Minor Assent Form (12 to 17)         7/30/2005           Guardian Signature" and updated signature lines to         Minor Assent Form (12 to 17)         7/30/2005           "Parent/Legal Guardian consent form to be used with the minor assent forms and the IRB recommendation to include a section to document the attestation of a counseling healthcare professional.         Protocol         7/30/2004           Protocol amended to include a statement that data from other factors) may be used for research purposes.         Protocol         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 to participate in the Research Database has been propared from the Consent to Donate. A new consent form has been prepared to combine the donor consent form hes usdy. Since the consent to participate in the Research from the donor consent form hes weren to allow donor to consent form.         7/30/2004           Consent to Donate form has been renoved from the study. Since the consent to participate in the Research from the Consent to Donate form has been renoved from the study. Since the consent to participate in the Research Recorib Tat	new PI	1	
légal rights by signing this form."       7/30/2005         Identify the NMDP IRB as the group of people who monitor       Donor Consent Section II       7/30/2005         Changed "Legal Guardian Consent's to "Parental/Legal Guardian Signature" and updated signature lines to       Minor Assent Form (7 to 11)       7/30/2005         "Prepared/Legal Guardian Consent form to be used with the minor assent forms       Minor Assent Form (12 to 17)       7/30/2005         "Attachment 1 updated to include sample language from revised consent forms and the IRB recommendation to include a statement that data from donor product tests (number and types of cells, sterility, other factors related to transplant       Protocol       7/30/2004         Section added to include Time-Point of "At the time of protocol, Section 4.2 Collection of Donor Data Paragraph 2       7/30/2004       7/30/2004         Collection" and Data Collected to include "Number of Donor Data Paragraph 2       7/30/2004       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 separated from the donor consent form the Research Database and Research Repository studies into one consent torm to the Research Batabase from to donor to consent torm to the Research Repository.       7/30/2004         Consent to Donate form has been removed from the Research Batabase and Research Parate activities" included and Research Repository.       7/30/2004		Donor Consent Section VIII	7/30/2005
Identify the NMDP IRB as the group of people who monitor       Donor Consent Section II       7/30/2005         Recipient Consent Section II       7/30/2005         Charged "Legal Guardian"       Minor Assent Form (12 to 17)         "PrenerLegal Guardian"       7/30/2005         Winth Prepared Parental/Legal Guardian consent form to be used       Minor Assent Form (12 to 17)         "Prepared Parental/Legal Guardian consent form to be used       7/30/2005         With the minor assent forms and the IRB recommendation to include a statement that data from include a section to document the attestation of a counseling healthcare professional.       Protocol         Protocol amended to include a statement that data from other factors) may be used for research purposes.       Protocol       7/30/2004         Section adde to include inme-Point of "At the time of product collection" and Data Collected to include "Number and type of cells, sterility. Other factors related to transplart"       Protocol       7/30/2004         Consent form re-written at a more appropriate reading level.       Recipient Consent form       7/30/2004         Research Database and Research Database has been prepared to combine the donor consent form has been removed from the Consent torm the donor consent form has been removed from the Consent torm and therefore does not require IRB approval.       Protocol       7/30/2004         Confirmatory Testing consent withdrawn from database and seearch Database and Research Database and Research Repository.       10/1/2003			
the use the data and protect the participant's rights.       Recipient Consent Section II         Changed "Legal Guardian Signature" and updated signature lines to       Minor Assent Form (7 to 11)       7/30/2005         Guardian Signature" and updated signature lines to       Minor Assent Form (12 to 17)       7/30/2005         "Prepared Parental/Legal Guardian consent form to be used with the minor assent forms       7/30/2004       7/30/2004         Attachment I updated to include sample language from include a section to document the attestation of a counseling healthcare professional.       Protocol       7/30/2004         Protocol amended to include a statement that data from other factors) may be used for research purposes.       Protocol Section 4.2 Collection of Donor Data, Time-point/Data and type of cells, Sterility, Other factors related to ramsplant"       7/30/2004         Consent form re-written at a more appropriate reading level.       Protocol, Section 4.2 Collection of Donor Data, Time-point/Data and type of cells, Sterility, Other factors related to ramsplant"       Donor Data, Time-point/Data and type of cells, Sterility, Other factors related to ramsplant"       Donor Consent form       7/30/2004         Consent to participate in the Research Database has been separated from the donors consent form has been repared to combine the donor consent form how replaced with combined donor to consent form.       7/30/2004         Database has been separated from the donors consent form the Consent to Donate form has been removed from the Research Database and Research Database and Research Database and Research Database a	legal rights by signing this form."		
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       Minor Assent Form (12 to 17)       7/30/2004         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       7/30/2004         Protocol amended to include a statement that data from product collection" and Data Collected to include "Number of Donor Data. Time-point/Data Collected chart       Protocol       7/30/2004         Consent form re-written at a more appropriate reading level.       Protocol, Section 4.2 Collection for 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 paparated from the Consent to participate in the donor consent for thas been prepared to combine the donor consent for thas been separated from the donors consent to consent form.       Previous Consent to Donate Form now replaced with combined consent form to allow donor to consent tor to Donate and therefore does not require IRB approval.       10/1/2003         Confirmatory Testing consent withdrawn from database tudy because all data collected during CT is used for strictly anonymous studies       Protocol: Section 2       10/1/2003		Donor Consent Section II	7/30/2005
Guardian Signature" and updated signature lines to       Minor Assent Form (12 to 17)         "Parent/Legal Guardian"       Minor Assent Form (12 to 17)         "Parent/Legal Guardian"       7/30/2005         Yepared Parental/Legal Guardian consent form to be used with the minor assent forms       7/30/2004         Attachment 1       updated to include sample language from lacthcare professional.       7/30/2004         Protocol       and the IRB recommendation to include a section to document the attestation of a counseling healthcare professional.       7/30/2004         Protocol amended to include Time-Point of "At the time of product collection" and Data Collected to include Time-Point of "At the time of product collection" and Data Collected to include Time-Point of "At the time of separated from the Consent tor Danate. A new consent form and type of cells, Sterility, Other factors related to transplant"       Protocol.       7/30/2004         Consent to participate in the Research Database has been separated from the Consent to Donate. A new consent form has been repared to combine the donor consent form has been separated from the donors consent form the study. Since the consent to participate in the Research Database and Been separated from the donors consent to the Research Database and Sheen separated from the donors consent form tow replaced with combined consent to Donate and therefore does not require IRB and mow replaced with combined consent form the Research Database and Research Da	the use the data and protect the participant's rights.	Recipient Consent Section II	
"Parent/Legal Guardian"       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 include a section to document the attestation of a counseling healthcare professional.       7/30/2004         Protocol       7/30/2004         Attachment 1 updated 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       7/30/2004         Section added to include Time-Point of "At the time of protocol. Section 4.2 Collection of Donor Data Paragraph 2       7/30/2004       7/30/2004         Consent form re-written at a more appropriate reading level.       Recipient Consent form       7/30/2004         Consent form to consent to Datate. A new consent form has been prepared to combine the donor consent for the Research Database nas been prepared to combine the donor consent for the Research Database and Research Repository studies into one consent form.       Now consent form to allow donor to consent for the Research activities" included and therefore does not require IRB approval.       10/1/2003         Confirmatory Testing consent withdrawn from database for Section 2       10/1/2003         Section added addressing tracking of donor consent for tor section 2       10/1/2003         Congranized Research Database Protocol to parallel Research Repository.       Protocol       10/1/2003         Confirmatory Testing consent withdrawn from dat	Changed "Legal Guardian Consent" to "Parental /Legal	Minor Assent Form (7 to 11)	7/30/2005
Prepared Parental/Legal Guardian consent form to be used       7/30/2005         with the minor assent forms       7/30/2004         Attachment 1       7/30/2004         Other factors) may be used for research purposes.       Data Paragraph 2         Section added to include Time-Point of "At the time of of Donor Data, Time-point/Data Collected to include "Number and type of cells, Sterility, Other factors related to transplant"       Collected chart         Consent form re-written at a more appropriate reading level.       Recipient Consent form       7/30/2004         Research Database and Research Database has been prepared to combine the donor consent form has been prepared to combine the donor consent form the Research Database has been separated from the donors consent to mover placed with combined consent form to Datate form has been removed from the Consent to Donate form has been removed from the donate, there are no longer any "research activities" included in the Consent to Donate form has been removed form the donate, there are no longer any "research activities" included and Research Repository.       7/30/2004         Confirmatory Testing consent withdrawn from database study because all data collected during CT is used for	Guardian Signature" and updated signature lines to	Minor Assent Form (12 to 17)	
with the minor assent forms       7/30/2004         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       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       7/30/2004         Section added to include Time-Point of "At the time of product collection" and Data Collected to include "Number"       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 donor consent for the Research Database and Research Repository studies into one consent form.       Donor Consent form       7/30/2004         The Consent to Donate form has been removed from the donors consent to and therefore does not require IRB and Research Repository.       Previous Consent form to allow donor to consent form to allow donor to consent to the donors consent to and therefore does not require IRB and Research Repository.       10/1/2003         Added Table of Contents       Protocol       10/1/2003         Section added addressing tracking of donor consent for bone marrow donation vs donor consent for participation in the Research Protocol Section 2       10/1/2003         Research Database <td< td=""><td></td><td></td><td></td></td<>			
Attachment 1 updated to include sample language from revised consent forms and the IRB recommendation to a conseling healthcare professional.       Protocol       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       7/30/2004         Section added to include Time-Point of "At the time of product collection" and Data Collected to include "Number and types of cells, Sterility, Other factors related to transplant"       Protocol       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 form the study. Since the consent to participate in the Research Database and Research Repository studies into one consent to Donate form has been removed from the donors consent to allow donor to consent to Donate and therefore does not require IRB approval.       Protocol       7/30/2004         Confirmatory Testing consent withdrawn from database study because all data collected during CT is used for strictly anonymous studies       Protocol       10/1/2003         Formatting changes:       Other form for participation 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	Prepared Parental/Legal Guardian consent form to be used		7/30/2005
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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