

RECORD OF REVISIONS:***Protocol for a Research Sample Repository for Allogeneic Hematopoietic Stem Cell Transplantation and Marrow Toxic Injuries (IRB-1991-0002)*****Current Protocol Version 6.0 (Continuing Review) – July 30, 2011**

Version 6.0 (Continuing) – July 30, 2010
 Version 5.1 (Continuing) – July 30, 2009
 Version 5.0 (Continuing) – July 30, 2008
 Version 4.1 (Continuing) – July 30, 2007
 Version 4.0 (Amendment) – April 26, 2007 (Effective 6/11/07)
 Version 3.0 (Continuing) – July 30, 2006
 Version 2.5 (Continuing) – July 30, 2005
 Version 2.4 (Amendment) – May 20, 2005
 Version 2.3 (Amendment) – May 1, 2005
 Version 2.2 (Continuing) – July 30, 2004
 Version 2.1 (Amendment) – January 28, 2004
 Version 2.0 (Continuing) – October 1, 2003
 Version 1.0 – July 2002

Description of Revision	Document/Section(s) Affected	Effective Date
Discontinued the consent form “Adult Registered Donor with Rare Tissue Type.” <i>(Although effective 7/30/2011, this change was not added to the Record of Revisions until 10/10/2011 due to an oversight.)</i>	Donor Consent Form: Adult Registered Donor with Rare Tissue Type	7/30/11
Paragraph 1: Last sentence, “You are being asked to participate because <u>you</u> have been exposed...”	Assent Forms: Minor Marrow Toxic Injury (12-17)	7/30/11
Paragraph 6: 2 nd sentence, “Your doctors or your parents cannot <u>will not</u> make you give the blood sample...”	Assent Forms: Minor Related Donor (12-17); Minor Allogeneic Recipient (12-17); Minor Marrow Toxic Injury (12-17)	7/30/11
Paragraph 2: Last sentence, “No identifiable information about your child will be <u>given to the researchers, nor will it be published or presented at scientific meetings.</u> ”	Donor Consent Forms (Section III): Minor Related Donor Parent/Legal Guardian Recipient Consent Forms (Section III): Minor Allogeneic Recipient Parent/Legal Guardian Marrow Toxic Injury Forms (Section III): Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/11
Paragraph 2: Last sentence, “No identifiable information about you will be <u>given to the researchers, nor will it be published or presented at scientific meetings.</u> ”	Donor Consent Forms (Section III): Adult Allogeneic Donor; Adult Registered Donor for Match Algorithm; Recipient Consent Forms (Section III): Adult Allogeneic Recipient; Marrow Toxic Injury Forms (Section III): Adult Marrow Toxic Injury;	7/30/11
Added second sentence to last paragraph: “Remember, you can change your mind at any time.”	Assent Forms: Minor Allo Recipient (7 to 11); Minor Marrow Toxic Injury (7 to 11)	7/30/10

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Added second sentence to last paragraph: “Remember, you can change your mind at any time and still give your special cells to your brother or sister.”	Assent Forms: Minor Related Donor (7 to 11)	7/30/10
Second paragraph: “If you agree to be in this research project, a nurse <u>someone</u> will take a small sample <u>amount</u> of blood...”	Assent Forms: Minor Marrow Toxic Injury (7 to 11)	7/30/10
Second paragraph: “If you want to be in this research project, your doctor <u>someone</u> will take a small amount...”	Assent Forms: Minor Related Donor (7 to 11); Minor Allo Recipient (7 to 11)	7/30/10
Moved the first sentence of the first paragraph, “You are <u>also</u> being invited to be in a research project with the NMDP and CIBMTR.” to be the fourth sentence.	Assent Forms: Minor Related Donor (7 to 11)	7/30/10
Paragraph 2: added second sentence “If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact a Patient Services Coordinator with the NMDP Office of Patient Advocacy at 1-888/999-6743 or patientinfo@nmdp.org.”	Recipient Consent Forms (Section IX): Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian Marrow Toxic Injury Forms (Section VIII): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/10
Paragraph 1: Deleted the sentence “NMDP will pay for this treatment.”	Donor Consent Forms (Section VIII): Minor Related Donor Parent/Legal Guardian	7/30/10
Paragraph 2; added second sentence “If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact NMDP Donor Advocacy at 1-800/526-7809, extension 8710.”	Donor Consent Forms (Section IX): Adult Related/Unrelated Donor; Minor Related Donor Parent/Legal Guardian; Adult Rare HLA Type Donor	7/30/10
Reworded first sentence as follows: “If you have questions, or <u>concerns, or complaints</u> about ...”	Donor Consent Forms (Section IX): Adult Related/Unrelated Donor; Minor Related Donor Parent/Legal Guardian; Adult Rare HLA Type Donor Recipient Consent Forms (Section IX): Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian Marrow Toxic Injury Forms (Section VIII): Adult Marrow Toxic Injury; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/10
Added directive to transplant centers at the end of the first paragraph that “For related donors, transplant centers should include their standard local language that addresses injury for research participants.”	Donor Consent Forms (Section VIII): Adult Related/Unrelated Donor	7/30/10
Added “for unrelated donors” at the end of the sentence	Donor Consent Forms (Section	7/30/10

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"NMDP will pay for this treatment."	VIII): Adult Related/Unrelated Donor	
Deleted the sentence: "Your child's blood sample will only be labeled with a number code."	Donor Consent Forms (Section III): Minor Related Donor Parent/Legal Guardian Recipient Consent Forms (Section III): Minor Allo Recipient Parent/Legal Guardian; Minor Marrow Toxic Injury Parent/Legal Guardian	7/30/10
Deleted the sentence: "Your blood sample will only be labeled with a number code."	Donor Consent Forms (Section III): Adult Related/Unrelated Donor; Adult Rare HLA Type Donor; Adult Match Algorithm Donor; Recipient Consent Forms (Section III): Adult Allo Recipient; Adult Marrow Toxic Injury	7/30/10
Changed two tablespoons to three tablespoons.	Donor Consent Forms (Section II): Adult Rare HLA Type Donor	7/30/10
In second paragraph, changed "characterization" to "study".	Donor Consent Forms (Section I): Adult Match Algorithm Donor	7/30/10
Clarified donor eligibility for rare allele and match algorithm enhancement activity	Protocol: Section 2.1	7/30/10
Changed volume to 50 mLs for donors with rare tissue types	Protocol: Section 4.1.4	7/30/10
Paragraph 2; added second sentence "If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact NMDP Donor Advocacy at 1-800/526-7809, extension 8710."	Donor Consent Form (Section IX): Adult Match Algorithm Donor	6/25/10
Reworded first sentence as follows: "If you have questions, or concerns, <u>or complaints</u> about ..."	Donor Consent Form (Section IX): Adult Match Algorithm Donor	6/25/10
Sentence 1: Changed two tablespoons to three tablespoons.	Donor Consent Form (Section III): Adult Match Algorithm Donor	6/25/10
Changed NMDP Suite Number to 100	Protocol: Title page	7/30/09
Changed version to 5.1	Protocol: Title page	7/30/09
Changed year to 2009	Protocol: Title page	7/30/09
Updated number of volunteer donors and transplants	Protocol: Section 1.1	7/30/09
Updated number of unique samples in repository	Protocol: Section 1.2	7/30/09
Added "Transplant Center "	Protocol: Section 4.2	7/30/09
Added line to write in Donor ID on each page of donor consents	Donor Consent Forms: Adult Related/Unrelated Donor; Adult Match Algorithm Donor; Adult Rare HLA Type Donor	7/30/09
Added "or tissue" to Section I, second paragraph, second sentence.	Donor Consent Forms: Adult Match Algorithm Donor; Adult Rare HLA Type Donor	7/30/09

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Reworded 3 rd bullet in Section I as follows: "Study the distribution of tissue types in different populations; e.g., for example, study tissue typing differences between different various racial and ethnic populations, to help develop methods that will to improve tissue matching between donors and recipients."	Donor Consent Forms: Adult Related/Unrelated Donor; Adult Match Algorithm Donor; Adult Rare HLA Type Donor; Minor Related Donor Parent/Legal Guardian; Recipient Consent Forms: Adult Allogeneic Recipient; Minor Allogeneic Recipient Parent/Legal Guardian	7/30/09
Added "and Marrow Toxic Injuries" to title.	Protocol: Title page	7/30/08
Updated number of donors and HSC transplants through December 2007.	Protocol: Section 1.1	7/30/08
Updated number of unique blood samples in research repository through May 2008.	Protocol: Section 1.2	7/30/08
Added delinked research as fourth type of study where samples could be used	Protocol: Section 1.2	7/30/08
Included use of donors for tissue type characterization and enhancement of search algorithm.	Protocol: Section 2.1	7/30/08
Created eligibility of individuals with marrow toxic injury.	Protocol: Section 2.4	7/30/08
Created sample collection from individuals with marrow toxic injury.	Protocol: Section 4.1.3	7/30/08
Created sample collection from donors for tissue type characterization and algorithm enhancement.	Protocol: Section 4.1.4	7/30/08
Added "and plasma."	Protocol: Section 5.1	7/30/08
Clarified that studies for delinked research follow the same review/approval process as outlined in Section 7.2 of the Protocol	Protocol: Section 8.2	7/30/08
Created consent form for donors for tissue type characterization and algorithm enhancement.	Adult Registered Donor for Match Algorithm Enhancement Consent Form	7/30/08
Created consent form for adults with marrow toxic injury.	Adult Marrow Toxic Injury Research Sample Consent Form	7/30/08
Created permission form for minors with marrow toxic injury.	Minor Marrow Toxic Injury Parent/Legal Guardian Permission Form	7/30/08
Created minor assent form for minors with marrow toxic injury (7 to 11 years old).	Minor Marrow Toxic Injury Assent Form (7 to 11 years of age)	7/30/08
Created minor assent form for minors with marrow toxic injury (12 to 17 years old).	Minor Marrow Toxic Injury Assent Form (12 to 17 years of age)	7/30/08
Revised wording regarding anonymous research to "In addition, investigators may conduct research studies with stored blood samples that have had all identifiers removed. In these studies, there will be no way for the sample to be linked to you. NMDP/CIBMTR may allow investigators to use these anonymous samples for many other kinds of studies. These studies are not limited to the types of studies listed above, or related to transplantation in general."	Consent Forms Section I	7/30/08
Removed the sentence "Your blood sample will be used to look at ways to improve how patients are matched with their donors."	Consent Forms Section II	7/30/08

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Added the sentence “Your blood sample will be frozen and stored indefinitely for possible use in future research studies.”	Consent Forms Section II	7/30/08
Added that studies must be reviewed by a group of scientists “within NMDP/CIBMTR as well as the Repository Oversight Committee.”	Consent Forms Section II	7/30/08
Removed mention that studies must be reviewed by the NMDP IRB and replaced it with “NMDP will also review the proposed study...”	Consent Forms Section II	7/30/08
Removed the sentence “An IRB is a group of people who protect the rights of research participants.”	Consent Forms Section II	7/30/08
Clarified “No identifiable information about you” rather than just “Your name”.	Consent Forms Section III	7/30/08
Added “Center for International Blood and Marrow Transplant Research (CIBMTR)” to title.	Consent Forms	7/30/08
Changed “study” to “project.”	Minor Assent Forms (7-11)	7/30/08
In last paragraph, changed “want to be in the research project” to “agree to give a small amount of blood for research.”	Minor Assent Forms (7-11)	7/30/08
Throughout form replaced various mentions of “in this study” to various mentions of “give a blood sample for research.”	Minor Assent Forms (12-17)	7/30/08
Removed “The NMDP would like the medical staff at your donor center to take”	Minor Related Donor Assent Form (12-17)	7/30/08
Removed “The NMDP would like your doctor to have one of the medical staff at your hospital take”	Minor Allogeneic Recipient Assent Form (12-17)	7/30/08
Added “including testing of rare HLA types” to the third bulleted type of research studies	Protocol: Section 1.2	7/30/07
Clarified that NMDP IRB review is done “administratively” by the NMDP IRB Chair	Protocol: Section 8.0	7/30/07
Clarified review of delinked research studies, documenting NMDP IRB review is done “administratively” by the NMDP IRB Chair	Protocol: Section 8.2	7/30/07
Revisions to section 2.4 <i>Informed Consent</i> , to include mention of assent and refer to parental consent as “permission”	Protocol: Section 2.4	7/30/07
Revisions to Minor Assent section to state local IRBs are responsible for determination of method to document minor assent	Protocol: Section 2.4.1	7/30/07
Include caveat that minor must be “capable of providing assent” and confirm parent/legal guardian permission is sufficient if minor lacks capacity to provide assent	Protocol: Section 2.4.1	7/30/07
Included language addressing use of samples for anonymous research	Consent Forms Section I	7/30/07
Revised mention of Parent/Legal Guardian “consent” to “permission” in title and section statement section	Legal Guardian Consent Forms	7/30/07
Added full board name for IRB	Consent Forms Section II	7/30/07
To avoid repetitive language, revised section III stating the NMDP/CIBMTR will try hard to avoid a loss of confidentiality to read “NMDP/CIBMTR have procedures in place to keep your data private”	Consent Forms Section III	7/30/07
Replaced use of “quitting” in two instances to “change your mind” and “this” in the withdrawal language	Consent Forms Section IV	7/30/07

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Updated site of Repository	Protocol: Section 1.2	6/11/07
Removed the option allowing centers to prepare site specific protocol	Protocol: Section 3	6/11/07
Updated section to include two sub-sections, one addressing collections for unrelated transplants and one addressing collections for related transplants	Protocol: Section 4.1	6/11/07
Included option for cell storage per “dried blood on filter paper”	Protocol: Section 5.1	6/11/07
Revised section to allow for NMDP IRB Chair administrative review for requests for samples – use of samples not considered “human research”	Protocol: Section 7.2	6/11/07
Added documentation that “Requestor will not receive any identifying information with the samples that could possibly be used to link the sample to the contributing individual.”	Protocol: Section 8.5	6/11/07
Added documentation that “The link will never be released to an investigator.”	Protocol: Section 10.1	6/11/07
Attachment removed – sites no longer allowed to prepare center specific protocol	Protocol: Attachment 1	6/11/07
Added CIBMTR to study invitation and referred to NMDP/CIBMTR throughout consent form	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor	6/11/07
For inclusion of related donors/recipients the types of studies for which samples may be used revised to state “understanding tissue matching of <u>related and unrelated</u> donors and recipients	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Rare HLA Type	6/11/07
Revised statement regarding NMDP IRB approval/ to reflect administrative review process “The studies will also be reviewed by the NMDP IRB to make sure the research is consistent with the types of studies described above. An IRB is a group of people who protect the rights of research participants.”	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Rare HLA Type	6/11/07
Revised language in Confidentiality section to state the NMDP/CIBMTR will not “intentionally” disclose subject’s participation and will make every effort to maintain strict confidentiality	Consent Forms: Recipient, Legal Guardian/Parent, Minor Assent Forms, Donor, Rare HLA Type	6/11/07
Prepared Parent/Legal Guardian consent form and Minor Assent forms for related donors requested to participate	New Consent Forms	6/11/07
Updated the number of unique blood samples included in the Repository to “over 38,000” as of May 2006	Protocol: Section 1.2	7/30/06
Clarified “parent <u>or legal guardian</u> ” as the entity responsible for providing permission for minors to participate	Protocol: Section 2.4.1	7/30/06
Minor modifications clarifying the NMDP IRB Office’s role in the IRB approval process for the Repository	Protocol: Section 3.1, 3.2	7/30/06
Updated the process by which requests for samples receive approval from the NMDP/CIBMTR	Protocol: Section 7.2	7/30/06
Revised wording regarding risks of collecting the blood sample from “may cause minor discomfort” to “ <u>will likely</u> cause minor discomfort”	Recipient Consent Section III Legal Guardian Consent Section III Rare Tissue Type Donor Consent Section III	7/30/06
Revised wording regarding risks of collecting the blood sample from “you might feel some pain” to “ <u>will probably</u> feel some pain”	Minor Assent Form (7-11) Minor Assent Form (12-17)	7/30/06

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Revised wording regarding risk of identification of participant from “small risk that someone could find out which blood sample is yours” to small risk that <u>an unauthorized person</u> could find out which blood sample is yours”	Recipient Consent Form Section III Legal Guardian Consent Form Section III Rare Tissue Type Donor Consent Form Section III	7/30/06
Added sentence “It is up to you if you want to participate in the Research Repository”	Recipient Consent Form Section VI Legal Guardian Consent Form Section VI Rare Tissue Type Donor Consent Form Section VI	7/30/06
Corrected voluntary participation and withdrawal language to “ <u>you and your child</u> ”	Legal Guardian Consent Form Section VI	7/30/06
Removed the phrase “My signature below says that” from the subject’s statement of consent	Recipient Consent Form Section X Legal Guardian Consent Form Section X Rare Tissue Type Donor Consent Form Section X	7/30/06
Discontinued use of donor consent combining language regarding participation in Research Repository and Research Database		7/30/06
Prepared separate consent form for donor participation in Research Sample Repository		7/30/06
New Principal Investigator	Protocol	7/30/05
Replaced Dennis Confer, M.D. with space to provide Donor Center Medical Director contact information	Donor Consent Section VIII	7/30/05
Corrected "You do not waive any liability rights for personal injury by signing this form" to "You do not waive any legal rights by signing this form."	Donor Consent Section VIII Donor w/ Rare Tissue Type Section VIII Recipient Consent Section VIII	7/30/05
Identification of the NMDP IRB as the group of people who monitor the use the data and protect the participant's rights.	Donor Consent Section II Recipient Consent Section II Donor w/ Rare Tissue Type Section II	7/30/05
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)	7/30/05
Prepared Parental/Legal Guardian consent form to be used with the minor assent forms		7/30/05
Protocol was revised, in accordance with the OHRP "Guidance on Research Involving Coded Private Information of Biological Specimens" to include a provision to obtain Cord Blood Unit (CBU specimens).	Protocol Sections: 2.2 (revised), 2.4 (revised), 2.4.2 (new), 4.2 (revised), and 5.1 (revised)	5/20/05
Volume of recipient blood sample reduced from 40mL to 20mL (three tablespoons to two tablespoons)	Protocol; Section 4.1, Attachment 1 Recipient Consent form; Section II	5/1/05
"Separation and..." removed from section 5.1 header	Protocol; Section 5.1	5/1/05
Removed language stating "When a recipient sample is received an attempt to made to isolate, collect and store peripheral blood mononuclear cells, granulocytes and	Protocol; Section 5.1	5/1/05

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serum."		
Removed "on every recipient sample received at the Repository and" and replaced with " <u>and recipient</u> "	Protocol; Section 5.2	5/1/05
Updated samples in the repository to reflect 32,000 as of April 2004	Protocol Section 1.2, Paragraph 1, Line 7	7/30/04
Revised the volume of donor sample that will be drawn. The volume has been changed from 30mL to 20mL for donors.	Protocol Section 4.1 Paragraph 3, Line 4	7/30/04
Attachment 1 updated to include sample language from revised consent forms and the IRB recommendation to include a section to document the attestation of a counseling healthcare professional.	Protocol Attachment 1	7/30/04
Added the mention of cord blood transplants to the NMDP goal of research	Rare Tissue Type Consent form Section I, Paragraph 2, Line 2,3	7/30/04
Added the mention of cord blood transplants to the NMDP goal of research.	Rare Tissue Type Consent form	7/30/04
Removed "HLA" since the revised language refers to HLA type as "tissue type" only.	Rare Tissue Type Consent form Section II, Paragraph 2, Line 2, 3	7/30/04
Changed the sentence to read "The studies must also be approved by a group of people who <i>monitor the use of your data and protect your rights.</i> "	Rare Tissue Type Consent form Section I, Bulleted Point 2	7/30/04
Changed the statement that the blood sample would not be used in any other research to the more correct statement that the sample "will be destroyed".	Rare Tissue Type Consent form Section VI, Paragraph 1, Line 2	7/30/04
Modified the format of the <i>Donor/Subject Statement of Consent</i>	Rare Tissue Type Consent form Section X	7/30/04
Consent form re-written at a more appropriate reading level	Recipient Consent form	7/30/04
Consent form re-written at a more appropriate reading level	Cord Blood Consent form	7/30/04
Consent form prepared to combine consent for donors to participate in both the Research Database and Research Repository studies.	Donor Consent form New consent form	7/30/04
Previous consent form for donor participation in Research Repository only, was removed from the study	Previous consent form for participation in Research Repository only, now replaced with combined consent form.	7/30/04
Added "registered" to the following sentence: ... donors and recipients who have either " <u>registered</u> ", donated or been transplanted...	Protocol Section 1.2, Paragraph 1, Line 5	1/28/04
Modified wording of "There are currently" to " <u>As of July 2003</u> there are over 29,000 unique blood samples in the NMDP Research Sample Repository."	Protocol Section 1.2, Paragraph 1, Line 7	1/28/04
Added section to address the types of studies that NMDP allows samples to be used without obtaining additional consent from the participants	Protocol Section 1.2, Paragraph 3	1/28/04
Paragraph added indicating registered donors with rare tissue types will be included as eligible participants in the Research Repository.	Protocol Section 2.1, Paragraph 2	1/28/04
Collection time for registered donors with rare tissue type added.	Protocol Section 4.1, Paragraph 3, Lines 2-4	1/28/04
Prepared an additional Research Repository consent form to be used by registered donors with rare tissue types	Consent form titled: <i>Contribution of a Blood Sample</i>	1/28/04

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	<i>to the National Marrow Donor Program's Research Sample Repository: Registered Donor with Rare Tissue Type Consent Form</i>	
Formatting changes Number of transplants updated Number of stored samples updated	Protocol Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject	10/1/03
Section added addressing justification of Minor Assent	Protocol Section 2	10/1/03
Section added outlining IRB approval process for centers contributing a research sample	Protocol Section 3	10/1/03
Revision to donor samples used for cell transformation	Protocol Section 5.2	10/1/03
Section added to address participant withdrawal from the Research Repository	Protocol Section 9	10/1/03
Attachment added defining minimum requirements set forth by the NMDP IRB for centers writing their own protocols and consent forms	Protocol Attachment 1	10/1/03
Reference to sample being separated into cells and plasma removed	Sections I, II Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
Phrase "ethnic" replaced with "racial and ethnic"	Sections I, II Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
Section added to address alternatives to participation	Section VII Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
The "Authorization to Use and Disclose Health Information for Research Purposes" removed	Recipient/Subject Consent Donor/Subject Consent Cord Blood Donor/Subject Consent	10/1/03
Statement "The NMDP will pay for this treatment." removed from consent form for recipients	Sections VIII Recipient/Subject Consent	10/1/03
"Unrelated donors" changed to "Cord Blood Units" or "CBUs"	Cord Blood Donor/Subject Consent	10/1/03
Minor Assent for ages 7 to 11 approved		10/1/03