



### Notice of Action

<b>Date:</b> July 18, 2011	<b>Study Number:</b> IRB-1991-0002
<b>Meeting Date:</b> July 14, 2011	
<b>Principal Investigator:</b> Stephen Spellman, M.S.	
<b>Study Title:</b> <i>Protocol for a Research Sample Repository for Allogeneic Hematopoietic Stem Cell Transplantation and Marrow Toxic Injuries</i>	
<b>Protocol Version:</b> T00007; Version 6.0	
<b>Number of participants approved:</b> <u>unlimited</u> Recipients/Donors	

**TYPE OF REVIEW:**

- Initial review
- Continuing review:**  **Open for enrollment**  Closed to accrual  Enrollment on hold
- Protocol amendment
- Consent form revision
- Final report
- Other \_\_\_\_\_

**STATUS:**

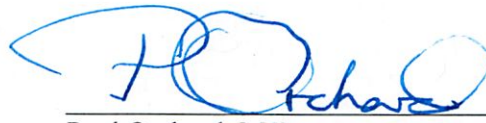
- Approved.**
  - No stipulations. Study may be initiated/continued.**
  - With stipulations – see attached.
- Stipulations have been met. Study may be initiated/continued.
- Stipulations have not been met – see attached.
- Deferred – see attached.
- Other \_\_\_\_\_

Term of approval: Jul | 30 | 2011 through Jul | 29 | 2012  N/A: Amendment Approved as of:

- All projects must be reviewed for continuation of work. No modification may be made in the protocol or in the wording of the IRB approved consent without the prior approval of the IRB.
- For donors not covered by the NMDP IRB, additional IRB approval from participating donor centers will be required.
- Donor/recipient consent forms are attached, if applicable.

Authorized signatories (only one required):

\_\_\_\_\_  
Roberta J. King, M.P.H. Date  
IRB Administrator

  
\_\_\_\_\_  
Paul Orchard, M.D. Date 7/26/2011  
IRB Chair

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For your information, the IRB stipulated the following changes to the NMDP consent forms. These changes have been made. (No response needed by you.)

1. **Section III, paragraph 2, sentence 3:** Revised the sentence, "No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings."

*This change was made to the following consent forms:*

- Adult Allogeneic Donor
- Adult Registered Donor for Match Algorithm Enhancement
- Minor Related Donor Parent/Legal Guardian
- Adult Allogeneic Recipient
- Minor Allogeneic Recipient Parent/Legal Guardian
- Adult Marrow Toxic Injury
- Minor Marrow Toxic Injury Parent/Legal Guardian

2. **Paragraph 6, sentence 2:** Revised the sentence, "Your doctors or your parents will not ~~cannot~~ make you give the blood sample if you don't want to."

*This change was made to the following consent forms:*

- Minor Related Donor Assent Form (12 to 17 years of age)
- Minor Allogeneic Recipient Assent Form (12 to 17 years of age)
- Minor Marrow Toxic Injury Assent Form (12 to 17 years of age)

3. **Paragraph 1, sentence 2:** Corrected the sentence, "You are being asked to participate because you have been exposed to radiation or other chemicals that..."

*This change was made to the following consent form:*

- Minor Marrow Toxic Injury Assent Form (12 to 17 years of age)