



**Thalassaemia Clinical Research Network and
Pediatric Bone Marrow Transplant Consortium**

**THALASSEMIA CLINICAL RESEARCH NETWORK (TCRN) and
WASHINGTON UNIVERSITY**

MEMORANDUM

Study Name: TCRN-NMD 0901- A Pilot Trial of Unrelated Donor Hematopoietic Cell Transplantation for Children with Severe Thalassaemia Using a Reduced Intensity Conditioning Regimen (The URTH Trial)

TO: TCRN and PBMTC sites participating in the URTH Trial

FROM: Shalini Shenoy, MD and Alexis Thompson, MD
URTH Study Co-Chairs

RE: TEMPORARY STUDY SUSPENSION FOR AMENDMENT

DATE: February 17, 2010

During a teleconference today, the joint protocol committee, which includes representatives from both the TCRN and the PBMTC, has determined that an amendment to the existing protocol is necessary prior to commencing patient enrollment. We will be working to get this out to participating sites ASAP. In light of this, we are recommending the following:

1. If you have not done so already, please POSTPONE submission to your IRB until the amendment is incorporated
2. If you have already submitted to your IRB, strongly consider requesting a withdrawal or hold on the review until the amended version can be submitted
3. If you have already received IRB approval, please WITHOLD ENROLLMENT until the amendment is in place
4. If you have consented patients, please DO NOT PROCEED TO TRANSPLANT until the amendment is approved at your institution. Do not proceed to transplant under the existing protocol and consents

The amendment is directed at increasing immunosuppression during conditioning in view of an increased risk of graft rejection in thalassaemia. We regret any concern or inconvenience that this suspension may create for your sites and/or your patients, but we believe that the proposed amendments will provide important changes to the protocol. We appreciate your willingness to participate. Please do call or e-mail us your questions.

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