



**Southwest  
Oncology Group**

A National Clinical Research Group

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TO: ALL SOUTHWEST ONCOLOGY GROUP AND BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK APPROVED AUTOLOGOUS BONE MARROW TRANSPLANT FACILITIES (See Section 19.2 or 19.3, respectively)

FROM: Gilbert R. Carrizales, M.S., Protocol Coordinator

RE: **S0410**, "Tandem Autologous Stem Cell Transplantation for Patients with Primary Progressive or Recurrent Hodgkin's Disease (A BMT Study), Phase II." Study Coordinators: E.P. Smith, P.J. Stiff, L.S. Constine, and L.M. Rimsza

**REVISION #6**

Study Coordinator: Eileen P. Smith, M.D.  
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**IRB Review Requirements**

- ( ) Full board review required. Reason:
  - ( ) Initial activation
  - ( ) Increased risk to patient
  - ( ) Complete study redesign
  - ( ) Addition of tissue banking requirements
  - ( ) Study closure due to new risk information
- (  ) Expedited review allowed
- ( ) No review required

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**REVISION #6**

The protocol referenced above has been revised as follows:

1. (Title page): The version date has been updated (version 11/15/07).
2. (Page 2): The mailing address for Dr. Lisa Rimsza has been corrected. "1501 North Campbell Avenue, Room 5211, Room 245043" has been changed to "1501 North Campbell Avenue, Room 5208, PO Box 245043".
3. (Page 17, Section 5.18, Eligibility Criteria; Fast Fact Sheet): "Patients must have adequate pulmonary function...performed within 28 days prior to initiation of stem cell mobilization" has been changed to "Patients must have adequate pulmonary function...performed *within 42 days prior to registration*". The Fast Fact Sheet has been updated accordingly.

*(Reason: This change allows centers to know the results of the pulmonary function tests before the patient is enrolled, and allows centers to perform the test after stem cell collection without any adverse impact on patient safety.)*

Please attach this memorandum to the front of your copy of the protocol and insert the replacement pages.

This memorandum serves to inform the NCI, the BMT CTN, and the Southwest Oncology Group Statistical Center.

cc: PROTOCOL & INFORMATION OFFICE  
Michael LeBlanc, Ph.D.  
Bryan Goldman, M.S.  
Joseph Unger, M.S.

Tracy Maher  
Jeri Jardine  
Colleen Allen – BMT-CTN

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**Operations Office**

