

CANCER AND LEUKEMIA GROUP B

PROTOCOL UPDATE TO CALGB 100103/BMT CTN 0502

A PHASE II STUDY OF ALLOGENEIC TRANSPLANT FOR OLDER PATIENTS WITH AML IN FIRST MORPHOLOGIC COMPLETE REMISSION USING A NON-MYELOABLATIVE PREPARATIVE REGIMEN

Limited Access Study: CALGB- and BMT CTN-Approved Allogeneic Transplant Centers

<input checked="" type="checkbox"/> Revision	<input checked="" type="checkbox"/> Amendment	<input type="checkbox"/> Status Change
<input type="checkbox"/> Change of participant(s)		<input type="checkbox"/> Activation
<input checked="" type="checkbox"/> Editorial, administrative changes		<input type="checkbox"/> Closure
<input type="checkbox"/> Scientific changes (IRB approval)		<input type="checkbox"/> Suspension
<input type="checkbox"/> Therapy changes (IRB approval)		<input type="checkbox"/> Reactivation
<input type="checkbox"/> Eligibility changes (IRB approval)		
<input type="checkbox"/> Informed Consent changes (IRB approval)		
<input type="checkbox"/> Other:		

***IRB review and approval of this update is required within 90 days.
Expedited IRB review is allowed. Sites should follow their local IRB guidelines.***

REVISIONS/AMENDMENTS:

Section 6.2 (Data Submission, page 11):

A second sentence has been added to the section: "This study will use NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 for routine toxicity reporting on study forms."

Replacement pages include cover page (page 1) and page 11.

ATTACH TO THE FRONT OF EVERY COPY OF THIS PROTOCOL
