



## **NCI Central IRB Study Activity Update**

**August 15, 2008**

The CIRB is distributing this study activity update to notify its participating institutions of recent information and documentation for current CIRB protocols. Information about protocol-specific addenda or memoranda issued by the Cooperative Groups, activations/closures of CIRB protocols, drug notices and safety reports, general CIRB memoranda and notices will be included in these broadcast summaries.

The protocol-specific information in this email refers to amendment/revision documentation approved by CIRB and NCI CTEP. Information about new studies refers to protocols that have been approved by the CIRB and NCI CTEP and activated by the Lead Cooperative Group.

These documents are posted within each protocol's document list inside the Participant's Area of the CIRB website ([www.ncicirb.org](http://www.ncicirb.org)). This is a protected site - you will be required to enter your username and password in order to access the Participant's Area. If you are unsure of your login information or have difficulty accessing the site/documents, please email [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) or call the CIRB at 888-657-3711.

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### General CIRB Documentation

If other individuals at your institution need to receive this email or other CIRB Correspondence please have them email [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) with their request.

**\*\*Note:** All documentation can be accessed through the What's New section of the CIRB website (<http://www.ncicirb.org>). **\*\***

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### Protocol Specific Documentation (listed by protocol)

**\*\*Note:** All documentation can be accessed through the Participant's Area ([http://www.ncicirb.org/CIRB\\_Login.asp](http://www.ncicirb.org/CIRB_Login.asp)) of the CIRB website. **\*\***



## Activity Posted:

### CALGB-50303

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### CALGB-70301

Continuing Review (CR) August 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/09/08)
- 08/12/08: CIRB Continuing Review Approval Letter (Protocol Version Letter 04/09/08)
- 07/11/08: Continuing Review Reminder Notice
- Protocol Version Date 04/09/08
- Informed Consent Document for Protocol Version Date 04/09/08 [Per Aug 08 CR]
- December 2007 - Study Summary

### CALGB-80203

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### CALGB-80303

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### CALGB-90202



Continuing Review (CR) June 2008 Approval Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**CALGB-90203**

Continuing Review (CR) June 2008 Approval Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**CALGB-90206**

Continuing Review (CR) June 2008 Approval Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**CALGB-90401**

Continuing Review (CR) June 2008 Approval Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**COG-AALL03B1**

Amendment Review (AR): **\*\*Partial Re-activation of Accrual of High-Risk B-precursor Patients by COG - Effective July 3, 2008\*\***

Documents Posted:

- 07/31/08: CIRB Acknowledgement of AALL03B1 Partial Reactivation of Accrual.....
- 07/03/08: Partial Reactivation of AALL03B1, Classification of Acute Lymphoblastic Leukemia (ALL)



#### COG-AEWS0521

Amendment Review (AR): **\*\*Reactivation of Accrual for One Additional Stratum 1 Patient - Effective July 18, 2008\*\***

Documents Posted:

- 07/31/08: CIRB Acknowledgement of AEWS0521 Reactivation of Accrual
- 07/18/08: Reactivation for One Additional Patient Accrual

#### COG-ANBL00B1

Continuing Review (CR): May 2008

Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### COG-ANBL0322

Continuing Review (CR): July 2008

Documents Posted:

- 08/05/08: CIRB Letter regarding ANBL0322 Closure and Continuing Review

#### COG-ANHL04B1

Continuing Review (CR): May 2008

Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### COG-AOST0331

Continuing Review (CR): May 2008

Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### COG-ARAR0331

Continuing Review (CR): June 2008



Documents Posted:

- 07/07/08: COG Response to Approval Pending Modification Letter - Revised (Protocol Version Date 05/25/05)

**ECOG-E1A00**

Continuing Review (CR) August 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/30/07)
- 08/12/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/30/07)
- 07/14/08: Continuing Review Reminder Notice
- Protocol Version Date 05/30/07 [Per Aug 08 CR]
- 04/30/08: Journal of Clinical Oncology
- 03/17/06: Journal of Clinical Oncology
- November 2004 - Study Summary
- 11/05/03: DMC Report

**ECOG-E1Y03**

Continuing Review (CR) July 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/15/06)
- 08/04/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/15/06)
- 07/14/08: Continuing Review Reminder Notice (Protocol Version Date 11/15/06)
- Protocol Version Date 11/15/06 [Per CR 08]
- Informed Consent Document for Protocol Version Date 11/15/06 [Per CR 08]

**ECOG-E1105**

Amendment Review (AR) Update #1 May 2008 Approval

Documents Posted:

- 11/09/07: Change Memo
- CIRB Application (Protocol Version Date 11/09/07)
- Summary of CIRB Application Revisions [Per Up 1]
- 05/29/08: CIRB Update 1 Approval Letter (Protocol Version Date 11/09/07)
- Protocol Version Date 11/09/07 [Per Up 1]
- Informed Consent Document for Protocol Version Date 11/09/07 [Per Up 1]
- 05/19/07: Primary Reviewer 1 Comments
- 05/19/07: Minutes - Update #1 Review



#### **ECOG-E1105**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E1505**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E2100**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E2805**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E3805**

Amendment Review (AR) Update #3 August 2008 Approval  
Documents Posted:

- 07/23/08: Change Memo (Protocol Version Date 07/23/08)
- CIRB Application (Protocol Version Date 07/23/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/23/08)
- 08/11/08: CIRB Update 3 Approval Letter (Protocol Version Date 07/23/08)
- Protocol Version Date 07/23/08 (Per Up3)
- Informed Consent Document for Protocol Version Date 07/23/08 [Per Up3]



#### **ECOG-E3805**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E4201**

Continuing Review (CR) August 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/07/07)
- 08/11/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/07/07)
- 06/06/08: Continuing Review Reminder Notice (Protocol Version Date 03/07/07)
- Protocol Version Date 03/07/07 [Per CR 08]
- 06/16/08: Study Update
- Study Summary - November 2007
- 09/24/07: DMC Recommendations

#### **ECOG-E4402**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E4A03**

Amendment Review (AR) June 2008 Approval-Addendum 7  
Documents Posted:

- 06/06/08: Minutes – Addendum 7 Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E4A03**

Continuing Review (CR) June 2008 Approval  
Documents Posted:



- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-PACCT-1**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **GOG-0209**

Amendment Review (AR) Revision #11 Approval Protocol Version Date 05/12/08  
Documents Posted:

- 05/12/08: Change Memo (Protocol Version Date 05/12/08)
- CIRB Application (Protocol Version Date 05/12/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/12/08)
- 08/11/08: CIRB Acknowledgement of Posting (Protocol Version Date 05/12/08)
- 06/24/08: CIRB Revision 11 Approval Letter (Protocol Version Date 05/12/08)
- Protocol Version Date 05/12/08 (Rev11)
- Protocol Version Date 05/12/08 (Highlighted)
- GOG-0209 Appendix I FIGO
- APPENDIX II NEW QOL COVER SHEET 5.14.03
- GOG-0209 Appendix III CTSU Participation Procedures 05.12.2008 Clean
- GOG-0209 Appendix III CTSU Participation Procedures 05.12.2008 with tracked changes
- Informed Consent Document for Protocol Version Date 05/12/08 [Per Rev11]
- 06/06/08: Minutes - Amendment Review-Revision 11

#### **GOG-0212**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **GOG-0213**



Continuing Review (CR) June 2008 Approval Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **GOG-0219**

Amendment Review (AR) Revision #6 Approval Protocol Version Date 05/22/08 Documents Posted:

- 05/22/08: Change Memo (Protocol Version Date 05/22/08)
- CIRB Application (Protocol Version Date 05/22/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/22/08)
- 08/08/08: CIRB Acknowledgement of Posting Revision 6
- 07/02/08: CIRB Revision 6 Approval Letter (Protocol Version Date 05/22/08)
- Protocol Version Date 05/22/08 (Per Rev6)
- Protocol Version Date 05/22/08 (Highlighted)
- GOG-0219 Appendix I (Extraperitoneal LNS)
- GOG-0219 Appendix II (Pelvic and PA Node Sampling)
- GOG-0219 Appendix III (FIGO)
- GOG-0219 Appendix IV (HDR Brachytherapy)
- GOG-0219 Appendix V (Blank Diagram Anterior)
- GOG-0219 Appendix VI (BLANK DIAGRAM LATERAL)
- GOG-0219 Appendix VII (ICRU Bladder Rectal Dose points)
- GOG-0219 Appendix VIII (RT for Canadian Sites)
- GOG-0219 Appendix IX Info for ANZGOG 02.06.2006
- GOG-0219 Appendix X Specimen Procedures 05.22.2008 Clean
- GOG-0219 Appendix X Specimen Procedures 05.22.2008 Highlighted
- GOG-0219 Appendix XI Laboratory Procedures 06.28.2006 effective 10.23.2006

#### **NCCTG-N06C6**

Continuing Review (CR) June 2008 Approval Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**



**NCCTG-N0147**

**\*\*Study will re-open to Accrual, effective August 18, 2008\*\***

Documents Posted:

- 08/13/08: CIRB Acknowledgement of Letter to Physicians on Re-Activation
- 08/06/08: NCCTG Notification of Re-Activation

**NCCTG-N0434 (MA.27D)**

**\*\*Permanently Closed to Accrual as of July 31, 2008 at 6:00 pm EST\*\***

Documents Posted:

- 08/11/08: CIRB Acknowledgement of Receipt of Closure to Accrual Notice
- 07/31/08: Notice of Status Change

**NCIC CTG-MA.27**

**\*\*Study Closed to Accrual Effective as of 6:00 pm EST on July 31, 2008\*\***

Documents Posted:

- 08/11/08: Acknowledgement of Permanent Study Closure

**NCIC CTG-MA.27**

Amendment Review (AR) April 2008 Approval

Documents Posted:

- 05/16/08: NCIC CTG "Important Change in Procedures" Letter

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**NCIC CTG-MA.27B**

Continuing Review (CR) June 2008 Approval

Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**NCIC CTG-PR.11**

Recruitment Materials (AR) June 2008 Approval

Documents Posted:

- 07/16/08: CIRB Approval Pending Modification of Recruitment Materials
- 06/09/08: Group Response to CIRB-Patient Recruitment Video
- 06/27/08: Primary Reviewer 1 Comments
- 06/27/08: Minutes - Group Response-Recruitment Materials



#### **NSABP-B-36**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **NSABP-B-38**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **NSABP-C-08**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **NSABP-C-09**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **RTOG-0126**

**\*\*Closed To Patient Accrual - Effective August 20, 2008 at 5pm EST\*\***

Documents Posted:

- 08/08/08: CIRB Acknowledgement of Closure to New Patient Accrual



#### **RTOG-0525**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **RTOG-0534**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **SWOG-S0221**

Continuing Review (CR) August 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/01/08)
- 08/01/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/01/08)
- 06/09/08: Continuing Review Reminder Notice (Protocol Version Date 01/01/08)
- Protocol Version Date 01/01/08 [Per CR 08]
- Informed Consent Document for Protocol Version Date 01/01/08 [Per CR 08]
- 07/18/08: SAE Report
- Study Summary - May 2008
- 05/02/08: DSMC Minutes
- Neupogen Description

#### **SWOG-S0232**

Continuing Review (CR) August 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/01/07)
- 08/13/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/01/07)
- 06/09/08: Continuing Review Reminder Notice
- Protocol Version Date 06/01/07
- May 1-4, 2008 - Study Summary



- 05/02/08: DSMC Minutes
- Abstract 8521 - 2008 ASCO Annual Meeting (Multiple Myeloma)

#### **SWOG-S0502**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **SWOG-S0521**

Continuing Review (CR) June 2008 Approval  
Documents Posted:

- 06/16/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### **Corrections to Previous Study Activity Updates**

#### **CALGB-30610**

Initial Review (IR) 2008

Documents Posted:

08/06/08: CIRB Correction Letter for Approval Pending Modification Letter dated 11/28/07

Correction: The CALGB 30610 approval letter pending modifications of the initial review of the study, dated November 28, 2007 contained an error. The body of the letter referenced the review date as November 11, 2007 instead of November 2, 2007.

#### **ECOG-E2603**

Amendment Review (AR) Addendum #10 Approval May 2008

Documents Posted:

Informed Consent Document for Protocol Version Date 04/03/08 [Per Add 10]

Correction: Informed Consent Document added to Addendum #10.



### ECOG-PACCT-1

Amendment Review (AR) Addendum #3 Approval May 2008

Documents Posted:

Informed Consent Document for Protocol Version Date 03/21/08 [Per Add 3]

Correction: Corrected formatting issue with last page (Study Plan).

### GOG-0219

Amendment Review (AR) Revision #3 Approval September 2006

Documents Posted:

08/06/08: CIRB Correction Letter for Amendment 3 Approval Letter dated 09/12/06

Correction: The GOG 0219 approval letter for Amendment # 3, dated September 12, 2006 contained an error. The body of the letter refers to an approval date on September 9, 2005 instead on September 9, 2006.

### RTOG-0415

Continuing Review (CR) Approval July 2008

Documents Posted:

Informed Consent Document [Tissue] for Protocol Version Date 12/03/07 (**for Currently Enrolled Patients**)

Correction: The phrase "**for Currently Enrolled Patients**" was added to the title of the Tissue Consent.

If you have any questions about your local review process, please contact your Local IRB office.

If you have any questions about the CIRB Initiative, please contact the CIRB at [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com).