



## NCI Central IRB Study Activity Update

June 30, 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. **\*\***



## **New Initial Approvals Posted:**

The new studies listed below have received CIRB approval and are entitled to facilitated review at your local IRB as part of the NCI CIRB initiative. You can download a completed application from the CIRB website along with the documents specified by your local IRB.

### **Adult CIRB Studies**

#### **CALGB-30607**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version Date 05/15/08
- Protocol Version Date 05/07/08
- Protocol Version Date 01/30/08
- Protocol Version Date 11/06/07
- Informed Consent Document for Protocol Version Date 05/15/08
- CIRB Application (Protocol Version Date 05/15/08)
- CIRB Application (Protocol Version Date 05/07/08)
- CIRB Application (Protocol Version Date 03/31/08)
- CIRB Application (Protocol Version Date 11/06/07)
- 03/07/08: Primary Reviewer 3 Comments
- 03/07/08: Primary Reviewer 4 Comments
- 12/07/08: Primary Reviewer 1 Comments
- 12/07/07: Primary Reviewer 3 Comments
- 12/07/07: Primary Reviewer 4 Comments
- 06/17/08: CIRB Acknowledgement of Activation (Protocol Version Date 05/15/08)
- 05/20/08: CIRB Final Approval Letter (Protocol Version Date 05/15/08)
- 05/20/08: CIRB Approval of Pre-Activation Amendment (Protocol Version Date 05/15/08)
- 05/16/08: CIRB Approval Letter (Protocol Version Date 05/15/08)
- 05/15/08: Group Response to PIO
- 05/12/08: PIO-CTEP Comments Requiring Response
- 05/08/08: CIRB Approval Letter (Protocol Version Date 05/07/08)
- 03/31/08: Group Response to CIRB
- 03/27/08: CIRB Approval Pending Modification of Group Response (Protocol Version Date 01/30/08)
- 01/30/08: Group Response to CIRB
- 01/09/08: CIRB Approval Pending Modification Letter (Protocol Version Date 11/06/07)
- 03/07/08: Minutes - Group Response - Initial Review
- 12/07/07: Minutes - Initial Review



- Appendix C- Specimen Banking Policies & Guide

### **RTOG-0436**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version Date 03/28/08
- Protocol Version Date 03/28/08 (Highlighted)
- Protocol Version Date 10/25/07
- Protocol Version Date 10/25/07 (Highlighted)
- Protocol Version Date 07/26/07
- Protocol Version Date 07/26/07 (Highlighted)
- Protocol Version Date 04/16/07
- Protocol Version Date 04/16/07 (Highlighted)
- Informed Consent Document for Protocol Version Date 03/28/08
- CIRB Application (Protocol Version Date 03/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 03/28/08)
- CIRB Application (Protocol Version Date 10/25/07)
- Summary of CIRB Application Revisions (Protocol Version Date 10/25/07)
- CIRB Application (Protocol Version Date 07/26/07)
- Summary of CIRB Application Revisions (Protocol Version Date 07/26/07)
- CIRB Application (Protocol Version Date 04/16/07)
- 11/08/07: Primary Reviewer 1 Comments
- 11/08/07: Primary Reviewer 4 Comments
- 11/08/07: Primary Reviewer 5 Comments
- 11/01/07: Primary Reviewer 1 Comments
- 11/01/07: Primary Reviewer 4 Comments
- 11/01/07: Primary Reviewer 5 Comments
- 05/27/08: CIRB Acknowledgement of Pre-Activation Notification (Protocol Version Date 03/28/08)
- 04/17/08: CIRB Approval Letter (Protocol Version Date 03/28/08)
- 12/03/07: CIRB Approval Letter (Protocol Version Date 10/25/07)
- 10/25/07: Group Cover Letter to CIRB
- 09/06/07: CIRB Table of Group Response to Initial Review (Protocol Version Date 07/26/07)
- 07/16/07: Group Cover Letter to CIRB
- 06/13/07: CIRB Table of Initial Review (Protocol Version Date 04/16/07)
- 11/08/07: Minutes - Group Response to Tabling of Initial Group Response
- 08/20/07: Minutes - Group Response to Initial Review
- 05/21/07: Minutes - Initial Review
- 03/28/08: Summary of Changes - Pre-Activation Revision

### **Pediatric CIRB Studies**



### **COG-AALL0622**

Initial Review 2008 Approval

Documents Posted:

- Protocol Version Date 03/28/08
- Protocol Version Date 03/28/08 - Highlighted Changes
- Protocol Version Date 10/08/07
- Protocol Version Date 10/08/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 03/28/08
- CIRB Application (Protocol Version Date 03/28/08)
- CIRB Application (Protocol Version Date 10/08/07)
- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Primary Reviewer 2 Comments
- 01/10/08: Primary Reviewer 3 Comments
- 01/10/08: Pharmacist Comments
- 05/28/08: CIRB Final Approval Letter (Protocol Version Date 03/28/08)
- 03/28/08: COG Response to Approval Pending Modification (Protocol Version Date 10/08/07)
- 01/25/08: CIRB Approval Pending Modification (Protocol Version Date 10/08/07)
- 01/10/08: Minutes - Initial Review

### **COG-ACCL0431**

Initial Review 2007 Approval

Documents Posted:

- Protocol Version Date 01/24/08
- Protocol Version Date 01/24/08 - Highlighted Changes
- Protocol Version Date 11/21/07
- Protocol Version Date 11/21/07 - Highlighted Changes
- Protocol Version Date 06/04/07
- Informed Consent Document for Protocol Version Date 01/24/08
- CIRB Application (Protocol Version Date 01/24/08)
- CIRB Application (Protocol Version Date 11/21/07)
- CIRB Application (Protocol Version Date 06/04/07)
- 12/12/07: Primary Reviewer 1 Comments
- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Primary Reviewer 2 Comments
- 08/23/07: Primary Reviewer 3 Comments
- 08/23/07: Pharmacist Comments
- 02/07/08: CIRB Approval Letter (Protocol Version Date 01/24/08)
- 01/24/08: COG Response to Approval Pending Modification (Protocol Version Date 01/24/08)



- 01/15/08: CIRB Approval Pending Modification of the Group Response (Protocol Version Date 11/21/07)
- 11/21/07: COG Response to Tabled Action Letter (Protocol Version Date 11/21/07)
- 09/25/07: CIRB Tabled Letter (Protocol Version Date 06/04/07)
- 12/13/07: Minutes - Group Response to Tabled Initial Review
- 08/23/07: Minutes - Initial Review

### **Other Activity Posted:**

#### **ACOSOG-Z1031**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/02/08: Primary Reviewer 1 Comments
- 05/02/08: Minutes - Continuing Review

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

#### **ACOSOG-Z4032**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/02/08: Primary Reviewer 1 Comments
- 05/02/08: 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-40101**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: 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-40503**

Continuing Review (CR): June 2008 Approval  
Documents Posted:



- CIRB Continuing Review Application (Protocol Version Date 02/14/08)
- 06/16/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/14/08)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 02/14/08
- Informed Consent Document for Protocol Version Date 02/14/08 [Per June 08 CR]

#### **CALGB-70301**

Amendment Review Update #4 Approval June 2008  
Documents Posted:

- 06/15/08: Change Memo (Protocol Version Date 04/09/08)
- CIRB Application (Protocol Version Date 04/09/08)
- Summary of CIRB Application Revisions (Protocol Version Date 04/09/08)
- 06/18/08: CIRB Acknowledgement of Activation (Protocol Version Date 04/09/08)
- 06/04/08: CIRB Update #4 Approval Letter (Protocol Version Date 04/09/08)
- Protocol Version Date 04/09/08
- Informed Consent Document for Protocol Version 04/09/08 [Per Up 4]

#### **CALGB-80203**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/09/07)
- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/09/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 02/09/07
- 06/16/08: Primary Reviewer 1 Comments
- Study Summary Dated June 2005

#### **CALGB-80303**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/17/07)
- 06/19/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/17/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 08/17/07
- Study Summary - June 2007
- Abstract 4508 Pancreatic Cancer - ASCO 2007



- Abstract 4525 Pancreatic Cancer - ASCO 2007
- Abstract 9008 Quality of Life - ASCO 2007

#### **CALGB-90104**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/26/07)
- 06/19/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
- 04/07/08: Continuing Review Reminder notice
- Protocol Version Date 03/26/07
- Study Summary - June 2006

#### **CALGB-90202**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/15/07)
- 06/17/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/15/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 11/15/07
- Informed Consent Document for Protocol Version Date 11/15/07 [PER June 08 CR]
- Study Progress Report - November 2007

#### **CALGB-90206**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/15/07)
- 06/19/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/15/07)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/15/07
- Study Summary - October 2007
- Abstract - Genitourinary Symposium

#### **CALGB-100104-ECOG 100104**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/02/08: Primary Reviewer 1 Comments



- 05/02/08: 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-100104-ECOG 100104**

Amendment Review Update #7 Approval May 2008

Documents Posted:

- 05/15/08: Change Memo (Protocol Version Date 04/04/08)
- CIRB Application (Protocol Version Date 04/04/08)
- Summary of CIRB Application Revisions (Protocol Version Date 04/04/08)
- 06/18/08: CIRB Acknowledgement of Activation (Protocol Version Date 04/04/08)
- 06/02/08: CIRB Update #7 Approval Letter (Protocol Version Date 04/04/08)
- Protocol Version Date 04/04/08
- Informed Consent Document for Protocol Version Date 04/04/08 [Per Up 7]
- 05/19/08: Minutes - Amendment Review Update #7
- 05/19/08: Primary Reviewer 1 Comments

#### **COG-AALL0433**

Amendment Review (AR): **\*\*Temporarily Closed to Accrual by COG - Effective June 17, 2008\*\***

Documents Posted:

- 06/26/08: CIRB Acknowledgement of AALL0433 Temporary Closure to Accrual
- 06/17/08: AALL0433 Temporary Suspension of Enrollment

#### **COG-AAML0121**

Amendment Review (AR): **Study Closed to Accrual by COG as of October 23, 2006 and completed as of October 1, 2007\*\***

Documents Posted:

- 03/24/08: CIRB Closure of AAML0121 Due to Study Completion
- 10/01/07: Study Progress Report
- 10/09/06: DSMC Report

#### **COG-ACCL04C2**

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: 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-ACNS0221**

Continuing Review (CR) Continuing Review August 2007  
Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: 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-ADVL0221**

Amendment Review (AR): **\*\*Temporarily Closed to Accrual by COG - Effective June 13, 2008\*\***

Documents Posted:

- 06/19/08: CIRB Acknowledgement of Temporary Study Closure to Accrual for ADVL0221
- 06/13/08: COG Memo Regarding Temporary Closure to Accrual for ADVL0221 Study

**COG-ANBL0322**

Amendment Review (AR): **\*\*Study Closed to Accrual by COG as of September 25, 2007 and completed as of January 8, 2008\*\***

Documents Posted:

- 04/08/08: CIRB Closure of ANBL0322 Due to Study Completion

**COG-AOST0331**

Amendment Review (AR): Amendment #2 (Protocol Version Date 09/21/07)  
Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Minutes - Amendment Review

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

**COG- ARST0431**

Amendment Review (AR): **\*\*Closed to Accrual by COG - Effective June 13, 2008 5 p.m. EST\*\***

Documents Posted:



- 06/19/08: CIRB Acknowledgement of Closure to Accrual for ARST0431
- 06/06/08: COG Memo Regarding ARST0431 Closure to Accrual

#### **ECOG-E1301**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/21/03)
- 06/05/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/21/03)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 08/21/03
- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: Minutes - Continuing Review
- Report of Studies Dated June 2005
- 11/02/04: DMC Report

#### **ECOG-E1302**

Amendment Review (AR): Addendum #8 (Protocol Version Date 04/16/08)  
Documents Posted:

- 04/16/08: Change Memo
- CIRB Application (Protocol Version Date 04/16/08)
- Summary of CIRB Application Revisions
- 05/29/08: CIRB Addendum #8 Approval Letter (Protocol Version Date 04/16/08)
- Protocol Version Date 04/16/08
- Informed Consent Document for Protocol Version Date 04/16/08 [Per Add 8]
- 05/19/08: Minutes - Amendment Review Addendum #8

#### **ECOG-E1302**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/19/08: 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:

- CIRB Continuing Review Application (Protocol Version Date 02/12/08)



- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/08)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 02/12/08
- Informed Consent Document for Protocol Version Date 02/12/08 [Per June 08 CR]
- 2007 ASCO Annual Meeting - Abstract LBA7514
- Study Summary Dated November 2007
- 09/24/07: DMC Recommendations

#### **ECOG-E3805**

Amendment Review (AR): Addendum #3 (Protocol Version Date 03/13/08)  
Documents Posted:

- 03/13/08: Change Memo (Protocol Version Date 03/13/08)
- CIRB Application (Protocol Version Date 03/13/08)
- Summary of CIRB Application Revisions (Protocol Version Date 03/13/08)
- 05/28/08: CIRB Addendum #3 Approval Letter (Protocol Version Date 03/13/08)
- Protocol Version Date 03/13/08
- Informed Consent Document for Protocol Version Date 03/13/08 [Per Add 3]
- 05/19/08: Minutes - Amendment Review Addendum #3

#### **ECOG-E3805**

Amendment Review (AR): Addendum #3 May 2008 Approval  
Documents Posted:

- 05/19/08: Minutes – Amendment Review Addendum #3

**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:

- CIRB Continuing Review Application (Protocol Version Date 05/30/07)
- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/30/07)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 05/30/07
- 06/16/08: Primary Reviewer 1 Comments
- Blood (ASH Annual Meeting Abstracts) 2007
- Report of Studies Dated November 2007



- 09/24/07: DMC Recommendations

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

Continuing Review (CR): June 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/21/08)
- 06/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/21/08)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 03/21/08
- Informed Consent Document for Protocol Version Date 03/21/08 [Per Jun 08 CR]
- 02/10/08: Journal of Clinical Oncology Article
- 09/24/07: DMC Recommendations
- Study Summary - Dated November 2007
- Group Tailorx Letter to Sites (Dr. Doctor)

#### **GOG-0198**

Continuing Review (CR): May 2008 Approval

Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: 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-0212**

Continuing Review (CR): June 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/08/08)
- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/08/08)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 02/08/08
- Informed Consent Document for Protocol Version Date 02/08/08 [Per Jun 08 CR]
- 06/16/08: Primary Reviewer 1 Comments
- 01/26/08: DSMB Minutes
- Study Summary

#### **GOG-0213**

Continuing Review (CR): June 2008 Approval



Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/01/08)
- 06/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/01/08)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 05/01/08
- Informed Consent Document for Protocol Version Date 05/01/08 [Per Jun 08 CR]
- 01/26/08: DSMB Minutes

**NCCTG-N06C6**

Continuing Review (CR): June 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/09/07)
- 06/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/09/07)
- 05/09/08: Continuing Review Reminder Notice (Protocol Version Date 11/09/07)
- Protocol Version Date 11/09/07
- Informed Consent Document for Protocol Version Date 11/09/07 [Per Jun CR 08]
- 04/08/08: DMC Report

**NCCTG-N0147**

Continuing Review (CR): May 2008 Approval

Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: 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-36**

Continuing Review (CR): June 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/20/07)
- 06/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/20/07)
- 05/23/08: Group Cover Letter
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 04/20/07



- Informed Consent Document for Protocol Version Date 04/20/07 [Per Jun 08 CR]
- 10/12/07: DMC Minutes
- Study Summary

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

Continuing Review (CR): June 2008 Approval Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/17/07)
- 06/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/17/07)
- 05/23/08: Group Cover Letter
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 04/17/07
- 05/23/08: Study Summary
- 10/12/07: DMC Minutes

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

Continuing Review (CR): June 2008 Approval Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/25/07)
- 06/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/25/07)
- 05/23/08: Group Cover Letter
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 10/25/07
- 06/16/08: Primary Reviewer 1 Comments
- 04/25/08: DMC Minutes
- 10/12/07: DMC Minutes
- Study Summary

#### **RTOG-BR-0118**

Continuing Review (CR): June 2008 Approval Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/31/03)
- 06/06/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/31/03)
- 03/05/08: Continuing Reminder Notice
- Protocol Version Date 10/31/03
- 01/11/08: DMC Minutes
- Study Summary - January 2005
- Publication Extract - Corn



- Publication Extract - Knisely

#### **RTOG-0129**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/31/05)
- 06/12/08: CIRB Continuing Review Approval Letter (Protocol Version 01/31/05)
- 06/02/08: Continuing Review Reminder Notice
- Protocol Version Date 01/31/05
- 01/11/08: DMC Minutes
- ASTRO - Abstract
- Study Summary - June 2007

#### **RTOG-0421**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/02/08: Primary Reviewer 1 Comments
- 05/02/08: 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-0525**

Amendment Review (AR):

**\*\*Closed to Accrual - Effective June 13, 2008 at 5pm EST\*\***

Documents Posted:

- 06/18/08: CIRB Acknowledgement of Receipt - Closure to Accrual

#### **RTOG-0525**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/30/07)
- 06/19/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/30/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 10/30/07
- Toxicity Report - January 2008
- 01/11/08: DMC Minutes



#### **SWOG-9007**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: 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-S0106**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: 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-S0309**

Continuing Review (CR): May 2008 Approval  
Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: 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-0502**

Continuing Review (CR): June 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/26/07)
- 06/12/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/26/07)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 11/26/07
- Informed Consent Document for Protocol Version Date 11/26/07 [Per June 08 CR]

#### **SWOG-0521**

Continuing Review (CR): June 2008 Approval  
Documents Posted:



- CIRB Continuing Review Application (Protocol Version Date 09/12/07)
- 06/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/12/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 09/21/07
- Informed Consent Document for Protocol Version Date 09/12/07 [Per Jun 08 CR]
- Study Summary - May 2008
- 10/11/07: DSMC Minutes

#### **SWOG-S9910**

Continuing Review (CR): May 2008 Approval Documents Posted:

- 05/10/08: Primary Reviewer 1 Comments
- 05/19/08: 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-S9925**

Continuing Review (CR): May 2008 Approval Documents Posted:

- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: Minutes - Continuing Review

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

### **Serious Adverse Events**

**Study: NSABP B-38**

**SAE Posted: US200803001632 FU1, FR200804000805 FU1, US200804003781, FR200802004113, FR200803000476, IN200802004040, US2008030001632, DE200610003194 FU1, IN200802004040 FU1, US200803003852, US200803003853**

**Study: NSABP B-40**

**SAE Posted: US200803001632 FU1, FR200804000805 FU1, US200804003781, 1199283 FU1, 1536472 FU1, FR200802004113, FR200803000476, IN200802004040, US2008030001632, 253571, 257657, 246935 FU3, 247544 FU2, 257028 FU1, 257876 FU1, DE200610003194 FU1, IN200802004040 FU1, 243768 FU2, 246872 FU2, 246934 FU1, 257876, US200803003852, US200803003853**



**Study: NSABP B-34**

**SAE Posted: 200820008 Safety Update 85, 200816556 Safety Update 84, 200816643 Safety Update 83, 200816063 Safety Update 80, 200816075 Safety Update 81, 200810824 FU2, 200813940 Safety Update 77 FU1, 200816114 Safety Update 82**

**Study: NSABP C-08**

**SAE Posted: 1199283 FU1, 1536472 FU1, 253571, 257657, 246935 FU3, 247544 FU2, 257028 FU1, 257876 FU1, 243768 FU2, 246872 FU2, 246934 FU1, 257876**

**Study: CALGB SWOG 80405**

**SAE Posted: 250866 FU1, 250367 FU2, 248756 FU2, 07-02-13307 FU1, 1425725, 1896903, 1129949, 07-02-12974, 246769, 07-02-12571, 1476709, 1024316, 248340**

**Study: CALGB 30607**

**SAE Posted: 1010206 FU1**

**Study: CALGB 40503**

**SAE Posted: 1199283 FU1, 1536472 FU1, 254163 FU2**

**Study: CALGB 40502**

**SAE Posted: 1536472 FU1**

**Study: CALGB 80203**

**SAE Posted: 1199283 FU1, 08-02-13981, 05-02-05850 FU3, 07-02-13171**

**Study: CALGB 90206**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: CALGB 90401**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: CALGB 100104**

**SAE Posted: 150-C5013-08020041 FU1**

**Study: ECOG 1A05**

**Study: 150-C5013-08020041 FU1**

**Study: ECOG 1A06**

**Study: 150-C5013-08020041 FU1**



**Study: ECOG 4A03**

**Study: 150-C5013-08020041 FU1**

**Study: ECOG E1105**

**Study: 1199283 FU1, 1536472 FU1**

**Study: ECOG E1305**

**Study: 1199283 FU1, 1536472 FU1**

**Study: ECOG E1505**

**Study: 1199283 FU1, 1536472 FU1**

**Study: ECOG E2100**

**Study: 1199283 FU1, 1536472 FU1**

**Study: ECOG 2805**

**Study: 1010206 FU1**

**Study: ECOG E4599**

**Study: 1199283 FU1, 1536472 FU1**

**Study: ECOG E5103**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: ECOG E5202**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: ECOG E5204**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: GOG 0213**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: GOG 0218**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: NCCTG N0147**

**SAE Posted: 1199283 FU1, 05-02-05850 FU3, 07-02-13171**

**Study: RTOG 0320**

**SAE Posted: 2006SP008904 FU2, 2006SP004547 FU1, 2006SP008904 FU3,  
2006SP004547 FU2, 2007SP003140 FU2, 2008SP000756 FU1**

**Study: RTOG 0436**

**SAE Posted: 1199283 FU1, 08-02-13981, 05-02-05850 FU3, 07-02-13171**



**Study: RTOG 0522**

**SAE Posted: 1199283 FU1, 08-02-13955, 08-02-14028, 08-02-13772 FU1, 07-02-13171, 05-02-05850 FU3**

**Study: RTOG 0525**

**SAE Posted: 2006SP008904 FU2, 2006SP004547 FU1, 2006SP008904 FU3, 2006SP004547 FU2, 2007SP003140 FU2, 2008SP000756 FU1**

**Study: SWOG S0232**

**Study: 150-C5013-08020041 FU1**

**Study: SWOG S0303**

**SAE Posted: 1108237, 1666966, 1900831**

**Study: SWOG S0502**

**SAE Posted: 1199283 FU1, 1536472 FU1**

**Study: SWOG S0518**

**SAE Posted: 1536472 FU1**

**Study: SWOG S0600**

**SAE Posted: 1199283 FU1, 1536472 FU1, 08-02-13981, 05-02-05850 FU3, 07-02-13171**

**Study: SWOG S0777**

**SAE Posted: 150-C5013-08020041 FU1**



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**Permanently Closed Studies, Re-Posted for you Convenience**

**CALGB-49808**

ADMINISTRATIVELY COMPLETED as of December 15, 2002

**GOG-0201**

COMPLETED (No Further Activity Being Conducted) as of April 28, 2005

**RTOG-P-0011**



ADMINISTRATIVELY COMPLETED as of May 7, 2004

**RTOG-P-0014**

ADMINISTRATIVELY COMPLETED as of February 4, 2005

**SWOG-S0227**

COMPLETED (No Further Activity Being Conducted) as of July 28, 2003

**SWOG-S0334**

COMPLETED (No Further Activity Being Conducted) as of June 15, 2007

**Corrections to Previous Study Activity Updates**

**ECOG E5103**

Amendment Review (AR) Update #2

Documents Posted:

Informed Consent Document for Protocol Version Date 012/26/07

Correction:

Incorrect Header replaced on consent for Update #2.

**GOG-0209**

Continuing Review (CR) November 2007 Approval

Documents Posted:

12/03/07: Group Suspension to Prior ERT Patients Memo

Correction:

Group notification to CIRB Memo added to Continuing Review correspondence.

**SWOG-S0337**

Continuing Review (CR) May 2008 Approval

Documents Posted:

Informed Consent Document for Protocol Version Date 05/01/07 (Per May 08 CR)

Correction:

Formatting error on page one corrected.

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).