



## NCI Central IRB Study Activity Update

March 14, 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**

#### **ECOG-E1A06**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version 08/31/07
- Protocol Version 05/16/07
- Protocol Version 01/16/07
- Informed Consent for Protocol Version 08/31/07
- CIRB Review Application (Protocol Version 08/31/07)
- Summary of CIRB Application Revisions (Protocol Version 8/31/07 & 5/16/07)
- CIRB Review Application (Protocol Version 05/16/07)
- CIRB Review Application (Protocol Version 01/16/07)
- 10/05/07: CIRB Initial Review Approval October 2007 (Protocol Version 08/31/07)
- 09/28/07: CTEP Approval on Hold (Protocol Version 08/31/07)
- 09/20/07: CTEP Recommendation Letter
- 06/25/07: CIRB Approval Pending Modification (Protocol Version 05/16/07)
- 05/03/07: CIRB Table of Initial Review (Protocol Version 01/16/07)
- 02/05/07: CTEP Approval on Hold (Protocol Version 01/16/07)
- 02/01/07: CTEP Recommendation Letter
- 01/26/07: CTEP Recommendation Letter
- 01/23/07: Group Response Letter
- 06/01/07: CIRB Meeting Minutes
- 04/06/07: CIRB Meeting Minutes

### **Pediatric CIRB Studies**

#### **COG – AEWS07P1**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version Date 10/12/07
- Protocol Version Date 10/12/07 - Highlighted
- Protocol Version Date 06/25/07
- Protocol Version Date 06/25/07 - Highlighted Version



- Informed Consent Form for Protocol Version Date 10/12/07
- CIRB Application (Protocol Version Date 10/12/07)
- CIRB Application (Protocol Version Date 06/25/07)
- 11/08/07: Primary Reviewer 1 Comments
- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Primary Reviewer 2 Comments
- 08/09/07: Pharmacist Comments
- 01/17/08: CIRB Final Approval (Protocol Version Date 10/12/07)
- 12/21/07: Group Response Letter
- 12/14/07: CIRB Approval Pending Modification (Protocol Version Date 10/12/07)
- 10/12/07: Group Response Letter
- 09/24/07: CIRB Approval Pending Modification August 2007 (Protocol Version Date 06/25/07)
- 06/25/07: Group Change Letter
- 11/08/07: Minutes - Group Response to Initial Review
- 08/09/07: Minutes - Initial Review

### **Other Activity Posted:**

#### **ACOSOG-Z1041**

Continuing Review (CR) Continuing Review November 2007 Approval Documents Posted:

- 11/01/07: Reviewer Comments

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

#### **ACOSOG-Z4032**

Amendment Review Amendment #1 (CTEP Amendment #3) Approval February 2008

Documents Posted:

- CIRB Review Application (Protocol Version 01/08/08)
- 02/11/08: CIRB Review Approval 02/01/08 (Protocol Version 01/08/08)
- 01/08/08: Group-PIO Letter
- Protocol Version 01/08/08
- Protocol Version 01/08/08 (Highlighted)
- Informed Consent for Protocol Version 01/08/08 [per Am 1 Mar 08]
- 01/31/08: Reviewer Comments
- 02/01/08: CIRB Meeting Minutes



#### **CALGB-49907**

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

- 02/22/08: CIRB Meeting Minutes

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

#### **CALGB-50305**

Continuing Review (CR) Continuing Review September 2007 Approval  
Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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

#### **CALGB-80101**

Continuing Review (CR) Continuing Review September 2007 Approval  
Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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

#### **CALGB/SWOG-80405**

Amendment Review Update #4 Approval January 2008  
Documents Posted:

- 11/08/07: Reviewer Comments
- 10/31/07: Reviewer Comments

**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) Continuing Review September 2007 Approval  
Documents Posted:

- 09/07/07: CIRB Meeting Minutes

**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**

Continuing Review (CR) Continuing Review September 2007 Approval Documents Posted:

- 09/17/07: CIRB Meeting Minutes

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

**COG – AALL03B1**

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

- 05/03/07: CIRB Continuing Review Reminder Notice

**COG – AALL03N1**

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

- 08/10/07: CIRB Continuing Review Reminder Notice

**COG – AALL0331**

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

- 05/03/07: CIRB Continuing Review Reminder Notice

**COG – AALL0433**

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

- 07/10/07: CIRB Continuing Review Reminder Notice

**COG – AALL0434**

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

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – AALL05B1**

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

- 04/12/07: CIRB Continuing Review Reminder Notice



**COG – AALL06N1**

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – AAML05P1**

Continuing Review (CR) Continuing Review December 2007

Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – AAML0523**

Continuing Review (CR) Continuing Review November 2007

Documents Posted:

- 09/11/07: CIRB Continuing Review Reminder Notice

**COG – AAML0531**

Continuing Review (CR) Continuing Review September 2007

Documents Posted:

- 07/10/07: CIRB Continuing Review Reminder Notice

**COG – AAML06P1**

Continuing Review (CR) Continuing Review December 2007

Documents Posted:

- 10/12/07: CIRB Continuing Review Reminder Notice

**COG – ABTR04B1**

Continuing Review (CR) Continuing Review September 2007

Documents Posted:

- 07/10/07: CIRB Continuing Review Reminder Notice

**COG – ACCL04C2**

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice



**COG – ACCL05C1**

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

- 10/12/07: CIRB Continuing Review Reminder Notice

**COG – ACNS0221**

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

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – ACNS0222**

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

- 10/12/07: CIRB Continuing Review Reminder Notice

**COG – ACNS0224**

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

- 05/03/07: CIRB Continuing Review Reminder Notice

**COG – ACNS0332**

Continuing Review (CR) Continuing Review January 2008  
Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – ACNS0334**

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

- 07/10/07: CIRB Continuing Review Reminder Notice

**COG – ACNS0423**

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

- 05/03/07: CIRB Continuing Review Reminder Notice



**COG – ADVL0221**

Continuing Review (CR) Continuing Review January 2008

Documents Posted:

- 12/14/07: CIRB Continuing Review Reminder Notice

Continuing Review (CR) Continuing Review April 2007

Documents Posted:

- 04/12/07: CIRB Continuing Review Reminder Notice

**COG – ADVL0524**

Continuing Review (CR) Continuing Review September 2007

Documents Posted:

- 07/10/07: CIRB Continuing Review Reminder Notice

**COG – ADVL0525**

Continuing Review (CR) Continuing Review July 2007

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – ADVL06B1**

Continuing Review (CR) Continuing Review February 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/29/07)
- 02/29/08: CIRB Approval to Continuing Review February 2008 (Protocol Version Date 11/29/07)
- 02/21/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/29/07
- Informed Consent Form for (Protocol Version Date 11/29/07)

**COG – AEWS0521**

Continuing Review (CR) Continuing Review September 2007

Documents Posted:

- 07/10/07: CIRB Continuing Review Reminder Notice



**COG – AEWS0621**

Continuing Review (CR) Continuing Review July 2007

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – AGCT0521**

Continuing Review (CR) Continuing Review October 2007

Documents Posted:

- 10/09/07: CIRB Continuing Review Reminder Notice

**COG – AHOD03P1**

Continuing Review (CR) Continuing Review August 2007 Approval

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – AHOD0431**

Continuing Review (CR) Continuing Review August 2007 Approval

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – AHOD0521**

Continuing Review (CR) Continuing Review February 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/01/07)
- 03/05/08: CIRB Approval to Continuing Review February 2008 (Protocol Version Date 05/01/07)
- 03/05/08: Group Response Letter
- 02/21/08: CIRB Approval Pending Modification to Continuing Review February 2008 (Protocol Version Date 05/01/07)
- 12/14/07: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/01/07
- Informed Consent Form for Protocol Version Date 05/01/07
- 10/16/07: DSMC Report
- Study Progress Report Dated 10/01/07

**COG – ANBL00B1**

Continuing Review (CR) Continuing Review July 2007

Documents Posted:

- 05/03/07: CIRB Continuing Review Reminder Notice



**COG – ANBL00P3**

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

- 08/14/07: CIRB Continuing Review Reminder Notice

**COG – ANBL0322**

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

- 05/03/07: CIRB Continuing Review Reminder Notice

**COG – ANBL0421**

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

- 04/12/07: CIRB Continuing Review Reminder Notice

**COG – ANBL0531**

Continuing Review (CR) Continuing Review January 2008  
Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – ANBL0532**

Continuing Review (CR) Continuing Review January 2008  
Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – ANHL04B1**

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

- 05/03/07: CIRB Continuing Review Reminder Notice

**COG – AOST0331**

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

- 04/12/07: CIRB Continuing Review Reminder Notice



**COG – AOST06B1**

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

- 09/27/07: CIRB Continuing Review Reminder Notice

**COG – ARAR0331**

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

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – ARAR0332**

Continuing Review (CR) Continuing Review December 2007 Approval  
Documents Posted:

- 10/12/07: CIRB Continuing Review Reminder Notice

**COG – AREN03B2**

Continuing Review (CR) Continuing Review January 2008  
Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – AREN0321**

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

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – AREN0532**

Continuing Review (CR) Continuing Review November 2007 Approval  
Documents Posted:

- 09/11/07: CIRB Continuing Review Reminder Notice

**COG – AREN0533**

Continuing Review (CR) Continuing Review December 2007 Approval  
Documents Posted:

- 10/12/07: CIRB Continuing Review Reminder Notice



**COG – ARET0231**

Continuing Review (CR) Continuing Review January 2008  
Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – ARET0321**

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

- 12/14/07: CIRB Continuing Review Reminder Notice

**COG – ARET0331**

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

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – ARET0332**

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

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – ARST03P1**

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

- 05/03/07: CIRB Continuing Review Reminder Notice

**COG – ARST0332**

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

- 08/10/07: CIRB Continuing Review Reminder Notice

**COG – ARST0431**

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

- 04/12/07: CIRB Continuing Review Reminder Notice



**COG – ARST0531**

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – ASCT0431**

Continuing Review (CR) Continuing Review January 2008

Documents Posted:

- 11/28/07: CIRB Continuing Review Reminder Notice

**COG – ASCT0631**

Continuing Review (CR) Continuing Review July 2007

Documents Posted:

- 06/08/07: CIRB Continuing Review Reminder Notice

**COG – D9902**

Continuing Review (CR) Continuing Review July 2007

Documents Posted:

- 05/03/07: CIRB Continuing Review Reminder Notice

**ECOG-E4A03**

Continuing Review (CR) Continuing Review September 2007 Approval

Documents Posted:

- 09/07/07: CIRB Meeting Minutes

**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) Continuing Review September 2007 Approval

Documents Posted:

- 09/07/07: CIRB Meeting Minutes

**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) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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

### **ECOG-E3200**

Continuing Review (CR) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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

### **ECOG-E3805**

Continuing Review (CR) Continuing Review September 2007 Approval Documents Posted:

- 09/17/07: CIRB Meeting Minutes

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

### **ECOG-E4402**

Continuing Review (CR) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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

### **ECOG-E5103**

Amendment Review Update #2 Approval January 2008 Documents Posted:

- CIRB Amendment Review Application (Protocol Version 12/26/07)
- Summary of CIRB Application Revisions (Update #2)
- 01/28/08: CIRB Update #2 Approval January 2008 (Protocol Version 12/26/07)
- 12/26/07: Group CTEP Change Letter



- Protocol Version 12/26/07
- Informed Consent for Protocol Version 12/26/07 (per Up #2)

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

- 02/22/08: CIRB Meeting Minutes

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

#### **ECOG-E5105**

Amendment Review Addendum #2 Approval February 2008 Documents Posted:

- CIRB Amendment Review Application (Protocol Version 02/07/08)
- Summary of CIRB Application Revisions
- 02/28/08: CIRB Addendum #2 Approval February 2008 (Protocol Version 02/7/08)
- 02/07/08: Group CTEP Letter
- Protocol Version 02/07/08
- Informed Consent for Protocol Version 02/07/08 [per Add 2 Feb 2008]

#### **ECOG-E5202**

Amendment Review Addendum #8 Approval February 2008 Documents Posted:

- CIRB Amendment Review Application (Protocol Version 06/12/07)
- Summary of CIRB Application Revisions
- 02/26/08: CIRB Addendum 8 Approval February 2008 (Protocol Version 6/12/07)
- 02/15/08: Group Response Letter
- 01/10/08: CIRB Response-NCI Revision Letter
- 10/17/07: Group Response Letter
- 08/02/07: CIRB Approval Pending Modification (Protocol Version 06/12/07)
- 06/12/07: Group CTEP Letter
- 10/26/04: CIRB Initial Review-Approval Pending Modification Letter (Protocol Version 10/13/04)
- 10/12/04: Group CTEP Letter
- 09/27/04: CIRB Initial Review Approval Pending Modification (Protocol Version 08/25/04)
- Protocol Version 06/12/07
- Informed Consent for Protocol Version 06/12/07 [per Add #8]
- 07/16/07: CIRB Meeting Minutes



### **ECOG-E6201**

Continuing Review (CR) Continuing Review September 2007 Approval Documents Posted:

- 09/17/07: CIRB Meeting Minutes

**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) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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

### **GOG-0212**

Amendment Review Revision #5 Approval February 2008 Documents Posted:

- CIRB Amendment Review Application (Protocol Version 02/08/08)
- Summary of CIRB Application Revisions
- 02/28/08: CIRB Revision #5 Approval February 2008 (Protocol Version 02/08/08)
- 02/08/08: Group-PIO Change Letter
- Protocol Version 02/08/08
- Protocol Version 02/08/08 (Track Changes)
- Appendix I: FIGO Stage Grouping for Primary Carcinoma
- Appendix II: Specimen Procedures for Translational Research
- Appendix III: Lab Procedures for Translational Research
- Appendix IV: Information on the Collection and Use of Specimens
- Appendix V: General Information
- Appendix VI: Instructions for Using the Web-Based Specimen Consent
- Informed Consent for Protocol Version 02/08/08 [per Rev 5 Feb 08]

### **GOG-0219**

Amendment Review Revision #5 Approval January 2008 Documents Posted:

- CIRB Amendment Review Application (Protocol Version 01/10/08)
- Summary of CIRB Application Revisions (Protocol Version 01/10/08)
- CIRB Amendment Review Application (Protocol Version 10/03/07)



- Summary of CIRB Application Revisions (Protocol Version 10/03/07)
- 03/04/08: CIRB Revision # 5 Approval January 2008 (Protocol Version 01/10/08)
- 01/10/08: Group Response
- 01/09/08: CIRB Approval Pending Modification
- 10/03/07: Group PIO Memo
- Protocol Version 01/10/08
- Protocol Version 01/10/08 (Track Changes)
- Protocol Version 10/03/07
- Protocol Version 10/03/07 (Track Changes)
- Appendix I (Extraperitoneal LNS)
- Appendix II (Pelvic and PA Node Sampling)
- Appendix III (FIGO)
- Appendix IV (HDR Brachytherapy)
- Appendix V (Blank Diagram Anterior)
- Appendix VI (Blank Diagram Lateral)
- Appendix VII (ICRU Bladder Rectal Dose points)
- Appendix VIII (RT for Canadian Sites)
- Appendix IX (info for ANZGOG 02/06/06)
- Appendix X Specimen Procedures
- Appendix XI Laboratory Procedures
- Appendix XII NCI DCTC Std Protocol Language
- Appendix XIII Logistical Guidelines for CTSU
- Informed Consent for Protocol Version 01/10/08 [per Jan 08 Rev5]
- 12/07/07: CIRB Meeting Minutes

Continuing Review (CR) Continuing Review November 2007 Approval Documents Posted:

- 11/01/07: Reviewer Comments

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

#### **NSABP-B-34**

Continuing Review (CR) Continuing Review November 2007 Approval Documents Posted:

- 11/08/07: Reviewer Comments
- 11/01/07: Reviewer Comments

**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) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

**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) Continuing Review September 2007 Approval Documents Posted:

- 09/17/07: CIRB Meeting Minutes

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

#### **NSABP-B-39-RTOG-0413**

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

- CIRB Continuing Review Application (Protocol Version 03/13/07)

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

#### **NSABP-B-42**

Continuing Review (CR) Continuing Review November 2007 Approval Documents Posted:

- 11/08/07: Reviewer Comments

**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) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

**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) Continuing Review September 2007 Approval Documents Posted:

- 09/17/07: CIRB Meeting Minutes

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

#### **NSABP -R-04**

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

- CIRB Continuing Review Application
- 02/11/08: CIRB Continuing Review Approval February 2008 (Protocol Version 06/12/07)
- 12/31/07: Group Cover Letter
- 11/26/07: CIRB Continuing Review Notice
- 08/09/07: Group Letter re: Information Associated with Use of Calcium & Magnesium
- Protocol Version 06/12/07
- Main Informed Consent for Protocol Version 06/12/07 [per Feb 08 CR]
- Informed Consent (Tissue) for Protocol Version 06/12/07 [per Feb 08 CR]
- 02/01/08: Primary Reviewer Comments
- Study Summary
- 10/12/07: DMC Minutes
- 04/13/07: DMC Minutes

#### **RTOG-0214**

Continuing Review (CR) Continuing Review October 2007 Approval Documents Posted:

- 10/08/07: Reviewer Comments

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

#### **RTOG-0320**

Continuing Review (CR) Continuing Review September 2007 Approval Documents Posted:

- 09/07/07: CIRB Meeting Minutes

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



#### **RTOG-0415**

Amendment Review (AR) Amendment #2 Approval November 2007

Documents Posted:

- 11/08/07: Reviewer Comments
- 10/31/07: Reviewer Comments

**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) Amendment #3 Approval November 2007

Documents Posted:

- 09/07/07: CIRB Meeting Minutes
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**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) Continuing Review November 2007 Approval

Documents Posted:

- 10/15/07: Reviewer Comments

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

#### **SWOG-S0421**

Continuing Review (CR) Continuing Review October 2007 Approval

Documents Posted:

- 11/01/07: Reviewer Comments

**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: RTOG 0320**

**SAE Posted: 2007SP007552(1), 2007SP012478, 2007SP014808, 2007SP014751(3), 2007SP0121156(2).**

**Study: RTOG 0525**



**SAE Posted: 2007SP007552(1), 2007SP012478, 2007SP014808, 2007SP014751(3), 2007SP0121156(2).**

**Study: RTOG 0522  
SAE Posted: DDL# 256/07-02-12635.**

**Study: NSABP B-38  
SAE Posted: AU200609000506, NL200708004927, US200708005949, RU200709003513(2), RU200709003513(1), JP200709000002.**

**Study: NSABP B-40  
SAE Posted: AU200609000506, NL200708004927, US200708005949, RU200709003513(2), RU200709003513(1), JP200709000002, 248340(1), 248750(1), 250243, 1896903, 1129949, 1425725, 250866, 250434(1), 250367(2), 248340(2), 247191(2), 235241(3), 248756(3), 250866(1), 252388.**

**Study: NSABP B-34  
SAE Posted: AU-2007-034510 Safety Update #54, GB-2007-028574, FR-2007-040962 Safety Update #59, US-2007-038539 Safety Update #58, LT-2007-038758 Safety Update #57, AU-2007-042893, Safety Update #63, Safety Update #64, Safety Update #65.**

**Study: NSABP C-08  
SAE Posted: 1425725, 1129949, 1896903, 248340(2), 235241(3), 248756(3), 250866(1), 252388.**

**Study: SWOG S0205  
SAE Posted: DDL# 256/07-02-12635**

**Study: SWOG 0502  
SAE Posted: 1425725**

**Study: SWOG 0518  
SAE Posted: 1425725**

**Study: SWOG 0303  
SAE Posted: 246769.**

**Study: SWOG 0600  
SAE Posted: DDL# 256/07-02-12635, 246769, 1425725.**

**Study: NCIC CTG MA27  
SAE Posted: NCIC CTG MA27-19, NCIC CTG MA27-18, NCIC CTG MA27-20, NCIC CTG MA27-22, NCIC CTG MA27-21, 2007094927(1).**

**Study: CALGB 90401**



**SAE Posted: 246769, 1896903, 1129949, 1425725.**

**Study: CALGB 90206**

**SAE Posted: 246769, 1896903, 1129949, 1425725.**

**Study: CALGB 80303**

**SAE Posted: 246769, 1896903, 1129949, 1425725.**

**Study: CALGB 100104**

**SAE Posted: 163-C5013-07071689(2)**

**Study: GOG 0213**

**SAE Posted: 246769, 1896903, 1129949, 1425725.**

**Study: GOG 0218**

**SAE Posted: 246769, 1896903, 1129949, 1425725.**

**Study: ECOG 1505**

**SAE Posted: 246769, 1896903, 1129949, 1425725.**

**Study: ECOG E2805**

**SAE Posted: 1776060, 1692621, 1896903, 1129949.**

**Study: ECOG 1A05**

**SAE Posted: 163-C5013-07071689(2)**

**Study: ECOG 1105**

**SAE Posted: 1896903, 1129949, 1425725.**

**Study: ECOG 2100**

**SAE Posted: 1896903, 1129949, 1425725.**

**Study: ECOG 2603**

**SAE Posted: 1896903, 1129949.**

**Study: ECOG 4599**

**SAE Posted: 1896903, 1129949, 1425725.**

**Study: ECOG 5103**

**SAE Posted: 1896903, 1129949, 1425725.**

**Study: ECOG 5202**

**SAE Posted: 1896903, 1129949, 1425725.**

**Study: ECOG 5204**

**SAE Posted: 1896903, 1129949, 1425725.**



**Study: ACOSOG Z1031**  
**SAE Posted: 1273276**

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

### **CALGB-40302**

Amendment Review Amendment 3-Update 2 Approval January 2008

Documents Posted:

- 01/02/08 (Revised 3/6/08): CIRB Update 2 Approval January 2008 (Protocol Version 12/11/07)

Correction:

Outcome Letter replaced.

### **CALGB-SWOG-80405**

Amendment Review Update #4 Approval January 2008

Documents Posted:

- Informed Consent for Protocol Version 12/18/07 (per Update #4)

Correction:

Removed Track Change version of consent and replaced with clean copy.

### **ECOG-E5103**

Amendment Review Update #1 Approval November 2007

Documents Posted:

- 11/26/07: CIRB Approval (Amendment#2-Local#1) November 2007 Protocol Version 11/02/07

Correction:

1. Outcome Letter replaced with revised version.
2. Update #1 was originally titled Amendment 2.
3. Study was incorrectly titled ECOG E5105 on the December 31, 2007 Study Activity update.

### **GOG-0209**

Amendment Review Revision #10 Approval January 2008

Documents Posted:

- Informed Consent for Protocol Version 01/14/08 (per Rev #10)

Correction:

Informed Consent was replaced with correct version.



### **GOG-0213**

Initial Review Approval October 2007

Documents Posted:

- Protocol Version 09/12/07

Correction:

Track Change version of protocol was replaced with clean copy.

### **RTOG-0415**

Amendment Review Amendment #2 Approval December 2007

Documents Posted: None

Correction:

Tissue Consent taken down from Web Site

### **RTOG-0525**

Amendment Review Amendment #3 Approval November 2007

Documents Posted:

- Informed Consent for Protocol Version 10/30/07 (per Am #3 Nov 07)

Correction:

Informed Consent replaced with revised version.

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).