



## NCI Central IRB Study Activity Update

February 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.

---

### 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>). **\*\***

---

### 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**

#### **NCCTG-N06C6**

Initial Review 2008 Approval

Documents Posted:

- Protocol Version 08/15/07
- Protocol Version 08/15/07 (Track Changes)
- Protocol Version 07/02/07
- Protocol Version 07/02/07 (Track Changes)
- Protocol Version 03/23/07
- CIRB Initial Review Application (Protocol Version 08/15/07)
- Summary of CIRB Application Revisions
- CIRB Initial Review Application (Protocol Version 07/02/07)
- Summary of CIRB Application Revisions (Protocol Version 07/02/07)
- CIRB Initial Review Application (Protocol Version 01/16/07)
- 02/12/08: CIRB Acknowledgement of Receipt of Activation
- 09/18/07: CIRB Initial Review Approval September 2007 Protocol Version 08/15/07
- 09/12/07: Group Response Letter
- 09/06/07: CIRB Follow Up Regarding Conference Call
- 08/22/07: CIRB Table of Initial Review
- 08/13/07: Group Response Letter
- 7/27/07: CIRB Table of Initial Review
- 07/02/07: Group Response Letter
- 06/13/07: CIRB Table of Initial Review
- 03/26/07: Approval on Hold (PIO)
- 09/17/07: CIRB Meeting Minutes
- 08/20/07: CIRB Meeting Minutes
- 08/03/07: CIRB Meeting Minutes
- 07/16/07: CIRB Meeting Minutes
- 06/01/07: CIRB Meeting Minutes



Amendment Review (AR): Patient Education Material Approval January 2008  
Documents Posted:

- 01/16/08: CIRB Approval of Recruitment Materials (Protocol Version 11/09/07)
- NCI Bone Study Patient Education Brochure

Amendment Review (AR): Amendment 1 Approval December 2007  
Documents Posted:

- CIRB Review Application (Protocol Version 11/09/07)
- Summary of CIRB Application Revisions
- 01/16/08: CIRB Review Approval December 2007 (Protocol Version 11/09/07)
- Protocol Version 11/09/07
- Informed Consent for Protocol Version 11/09/07 [per Am 1]
- 12/07/07: CIRB Meeting Minutes

#### **RTOG-0534**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version 10/03/07
- Protocol Version 10/03/07 (Track Changes)
- Protocol Version 06/29/07
- Informed Consent for Protocol Version 10/03/07
- CIRB Initial Review Application (Protocol Version 10/03/07)
- Summary of CIRB Application Revisions (Protocol Version 10/03/07)
- CIRB Initial Review Application (Protocol Version 06/29/07)
- 10/15/07: CIRB Initial Review Approval October 2007 (Protocol Version 10/03/07)
- 10/03/07: Group Response Letter
- 08/22/07: CIRB Approval Pending Modifications
- 06/29/07: Group Change Memo
- 05/09/07: CTEP Approval on Hold
- 08/03/07: CIRB Meeting Minutes



## **Pediatric CIRB Studies**

### **COG – ADVL06B1**

Initial Review 2007 Approval

Documents Posted:

- Protocol Version Date 05/24/07
- Protocol Version Date 05/24/07 - Highlighted Version
- Protocol Version Date 02/13/07
- Protocol Version Date 02/13/07 - Highlighted Version
- CIRB Application (Protocol Version Date 05/24/07)
- CIRB Application (Protocol Version Date 02/13/07)
- 06/14/07: Primary Reviewer 1 Comments
- 04/12/07: Primary Reviewer 1 Comments
- 04/12/07: Primary Reviewer 2 Comments
- 04/12/07: Primary Reviewer 3 Comments
- 06/25/07: CIRB Final Approval June 2007 (Protocol Version Date 05/24/07)
- 05/24/07: Group Response Letter
- 04/30/07: CIRB Approval Pending Modification to Initial Review April 2007 (Protocol Version Date 02/13/07)
- 06/14/07: Minutes - Group Response to Initial Review
- 04/12/07: Minutes - Initial Review

### **COG – AEWS07B1**

Initial Review 2007 Approval

Documents Posted:

- Protocol Version Date 10/19/07
- Protocol Version Date 10/19/07 Highlighted Version
- Protocol Version Date 07/26/07
- Protocol Version Date 07/26/07 Highlighted Version
- Protocol Version Date 03/30/07
- CIRB Ancillary Application (Protocol Version Date 10/19/07)
- CIRB Ancillary Application (Protocol Version Date 07/26/07)
- CIRB Ancillary Application (Protocol Version Date 03/30/07)
- 09/27/07: Primary Reviewer 1 Comments
- 06/14/07: Primary Reviewer 1 Comments
- 06/14/07: Primary Reviewer 2 Comments
- 06/14/07: Primary Reviewer 3 Comments
- 10/24/07: CIRB Final Approval (Protocol Version Date 10/19/07)
- 10/19/07: Group Response Letter (Protocol Version Date 10/19/07)
- 10/15/07: CIRB Approval Pending Modification (Protocol Version Date 07/26/07)
- 07/26/07: Group Response Letter (Protocol Version Date 07/26/07)



- 07/13/07: CIRB Approval Pending Modification (Protocol Version Date 03/30/07)
- 3/30/07: Group Response Letter to CTEP
- 09/27/07: Minutes - Group Response to Initial Review
- 06/14/07: Minutes - Initial Review

### **COG - AOST06B1**

Initial Review 2006 Approval  
Documents Posted:

- Protocol Version Date 06/10/07
- Protocol Version Date 06/10/07 - Highlighted Version
- Protocol Version Date 04/18/07
- Protocol Version Date 04/18/07 - Highlighted Version
- Protocol Version Date 02/02/07
- Protocol Version Date 02/02/07 - Highlighted Version
- Protocol Version Date 08/21/06
- CIRB Application (Protocol Version Date 06/10/07)
- CIRB Application (Protocol Version Date 04/18/07)
- CIRB Application (Protocol Version Date 02/02/07)
- CIRB Application (Protocol Version Date 08/21/06)
- 07/12/07: Primary Reviewer 1 Comments
- 05/10/07: Primary Reviewer 1 Comments
- 03/08/07: Primary Reviewer 1 Comments
- 12/28/06: Primary Reviewer 1 Comments
- 12/28/06: Primary Reviewer 2 Comments
- 12/28/06: Primary Reviewer 3 Comments
- 07/24/07: CIRB Final Approval July 2007 (Protocol Version Date 06/10/07)
- 06/10/07: Response Letter
- 05/29/07: CIRB Approval Pending Modification May 2007 (Protocol Version Date 04/18/07)
- 04/18/07: Group Response Letter
- 04/17/07: CIRB Approval Pending Modification of the Group Response to Initial Review (Protocol Version Date 02/02/07)
- 02/02/07: Response Letter
- 07/12/07: Minutes - Group Response to Initial Review
- 05/10/07: Minutes - Group Response to Initial Review
- 03/08/07: Minutes - Group Response to Initial Review
- 12/28/06: Minutes - Initial Review



## **COG - ARET0321**

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 03/05/07
- Protocol Version Date 03/05/07 - Highlighted Version
- Protocol Version Date 01/02/07
- Protocol Version Date 01/02/07 - Highlighted Version
- Protocol Version Date 07/07/06
- Protocol Version Date 07/07/06 - Highlighted Version
- Protocol Version Date 04/03/06
- Protocol Version Date 04/03/06 - Highlighted Version
- Protocol Version Date 10/24/05
- CIRB Application (Protocol Version Date 01/02/07)
- CIRB Application (Protocol Version Date 07/07/06)
- CIRB Application (Protocol Version Date 04/03/06)
- CIRB Application (Protocol Version Date 10/24/05)
- 02/08/07: Primary Reviewer 1 Comments
- 05/11/06: Primary Reviewer 1 Comments
- 05/11/06: Primary Reviewer 2 Comments
- 01/12/06: Primary Reviewer 1 Comments
- 01/12/06: Primary Reviewer 2 Comments
- 01/12/06: Primary Reviewer 3 Comments
- 01/12/06: Pharmacist Comments
- 03/27/07: CIRB Final Approval (Protocol Version Date 03/05/07)
- 02/26/07: CIRB Approval Pending Modification of Initial Review February 2007 (Protocol Version Date 01/02/07)
- 01/02/07: Group Response Letter
- 08/16/06: Group Response Review Tabled
- 07/07/06: Group Response Letter to CIRB Table of Initial Review
- 05/15/06: CIRB Approval Pending Modification to Initial Review (Protocol Version Date 04/03/06)
- 04/03/06: Group Response Letter to CIRB Table of Initial Review (Protocol Version Date 10/24/05)
- 02/02/06: CIRB Table of Initial Review (Protocol Version Date 10/24/05)
- 10/24/05: Cover Memo
- 02/08/07: Minutes - Group Response to Initial Review
- 05/11/06: Minutes - Group Response to Tabled Action
- 01/12/06: Minutes - Initial Review



## **Other Activity Posted:**

### **CALGB-30102**

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application [Protocol Version 08/07/03]
- 01/23/08: CIRB Continuing Review Approval January 2008 Protocol Version 08/07/03
- 12/11/07: CIRB Continuing Review Notice Protocol Version Date 08/07/03
- June 2005: Study Summary

### **CALGB-90202**

Amendment Review (AR): Update #7 Approval December 2007

Documents Posted:

- 11/15/07: Change Memo
- CIRB Application (Protocol Version 11/15/07)
- Summary of CIRB Application Revisions
- 12/18/07: CIRB Amendment Review Update#7 Approval (Protocol Version 11/15/07)
- Protocol Version 11/15/07
- Informed Consent Form for Protocol Version 11/15/07 [per Update#7]

### **COG – AAML0531**

Continuing Review (CR): September 2007

Documents Posted:

- 09/27/07: Primary Reviewer 1 Comments
- 09/27/07: Minutes - Continuing Review

### **COG – ACNS0332**

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/15/07)
- 02/06/08: CIRB Approval to Continuing Review January 2008 (Protocol Version Date 02/15/07)
- 01/24/08: Group Response Letter
- 01/18/08: CIRB Approval Pending Modification to Continuing Review January 2008 (Protocol Version Date 02/15/07)
- Protocol Version Date 02/15/07
- Informed Consent Form Protocol Version Date 02/15/07



- 10/16/07: DSMC Report
- Study Progress Report Dated 10/01/07

#### **COG – ACNS0334**

Amendment Review (AR): Amendment Review (Protocol Version Date 06/15/07)  
Documents Posted:

- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Minutes – Amendment Review

#### **COG – ADVL0221**

Amendment Review (AR): Activation Amendment (Protocol Version  
Date 11/06/07)  
Documents Posted:

- 11/30/06: Primary Reviewer 1 Comments
- 11/30/06: Minutes – Group Response to Amendment Review

#### **COG – ADVL0524**

Amendment Review (AR): Amendment #2 (Protocol Version Date 10/01/07)  
Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 03/08/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes – Amendment Review
- 03/08/07: Minutes – Amendment Review

#### **COG – ADVL06B1**

Amendment Review (AR): Activation Amendment (Protocol Version  
Date 11/29/07)  
Documents Posted:

- CIRB Application (Protocol Version Date 11/29/07)
- 01/03/08: CIRB Approval to Activation Amendment December 2007  
(Protocol Version Date 11/29/07)
- 11/29/07: Group Change Letter
- Protocol Version Date 11/29/07
- Protocol Version Date 11/29/07 - Highlighted Version
- Informed Consent Form for (Protocol Version Date 11/29/07)



### **COG – AEWS07B1**

Amendment Review (AR): Activation Amendment (Protocol Version Date 12/27/07)

Documents Posted:

- CIRB Ancillary Application Protocol Version Date 12/27/07
- 01/28/08: CIRB Activation Amendment Approval January 2008 (Protocol Version Date 12/27/07)
- 12/27/07: Group Cover Letter
- Protocol Version Date 12/27/07
- Protocol Version Date 12/27/07 Highlighted Version
- Informed Consent Form for Protocol Version Date 12/27/07 - Initial Diagnosis
- Informed Consent Form for Protocol Version Date 12/27/07 - Recurrence

### **COG – ANBL0322**

Amendment Review (AR): Amendment #2 (Protocol Version Date 03/28/07)

Documents Posted:

- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Minutes - Amendment Review

Amendment Review (AR): CIRB Acknowledge of Memo re: Closure of Stratum 2

Documents Posted:

- 05/10/07: Primary Reviewer 1 Comments
- 05/10/07: Minutes - Group Response to Amendment Review

### **COG – ANBL0531**

Initial Review 2006

Documents Posted:

- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Minutes – Group Response to Initial Review

### **COG – ANBL0532**

Continuing Review (CR): January 2008

Documents Posted:

- 01/18/08: CIRB Approval Pending Modification to Continuing Review January 2008 (Protocol Version Date 05/29/07)



### **COG - AOST06B1**

Amendment Review (AR): Activation Amendment #1

Documents Posted:

- CIRB Application (Protocol Version Date 11/26/07)
- 01/03/08: Approval to Activation Amendment December 2007 (Protocol Version Date 11/26/07)
- 11/20/07: Change Letter
- Protocol Version Date 11/26/07
- Protocol Version Date 11/26/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 11/26/07 - Newly-Diagnosed Osteosarcoma
- Informed Consent Form for Protocol Version Date 11/26/07 - Recurrent Osteosarcoma

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/10/07)
- 10/12/07: CIRB Approval to Continuing Review October 2007 (Protocol Version Date 06/10/07)
- Protocol Version Date 06/10/07

### **COG – AREN03B2**

Continuing Review (CR): January 2008

Documents Posted:

- 01/18/08: CIRB Approval Pending Modification to Continuing Review January 2008 (Protocol Version Date 03/20/07)
- CIRB Continuing Review Application (Protocol Version Date 03/20/07)

Continuing Review (CR): March 2007

Documents Posted:

- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Minutes – Continuing Review

Continuing Review (CR): May 2006

Documents Posted:

- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Minutes – Continuing Review



### **COG – ARET0231**

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/26/07)
- 02/06/08: CIRB Approval to Continuing Review January 2008 (Protocol Version Date 09/26/07)
- 01/22/08: CIRB Response Letter
- 01/21/08: CIRB Approval Pending Modification to Continuing Review January 2008 (Protocol Version Date 09/26/07)
- Protocol Version Date 09/26/07
- Informed Consent Form for Protocol Version Date 09/26/07
- 10/16/07: DSMC Report
- Study Progress Report Dated 10/01/07

Amendment Review (AR): Amendment #1 (Protocol Version Date 09/26/07)

Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes – Amendment Review

### **COG – ARET0321**

Amendment Review (AR): Activation Amendment (Protocol Version Date 08/08/07)

Documents Posted:

- CIRB Application (Protocol Version Date 08/08/07)
- CIRB Application (Protocol Version Date 05/02/07)
- 10/08/07: CIRB Approval (Protocol Version Date 08/08/07)
- 08/08/07: Group Response Letter to CIRB Table
- 07/20/07: CIRB Approval Pending Modification of Amendment July 2007 (Protocol Version Date 05/02/07)
- 05/02/07: Group Response Letter
- Protocol Version Date 08/08/07
- Protocol Version Date 08/08/07 Highlighted Version
- Protocol Version Date 05/02/07
- Protocol Version Date 05/02/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 08/08/07 - Stage 2 and 3
- Informed Consent Form for Protocol Version Date 08/08/07 - Stage 4a and 4b
- 09/27/07: Primary Reviewer 1 Comments
- 07/12/07: Primary Reviewer 1 Comments
- 09/27/07: Minutes - Group Response to Amendment Review
- 07/12/07: Minutes - Amendment Review



Continuing Review (CR): January 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/08/07)
- 01/28/08: CIRB Approval to Continuing Review January 2008 (Protocol Version Date 08/08/07)
- Protocol Version Date 08/08/07

Continuing Review (CR): April 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/05/07)
- 04/17/07: CIRB Approval to Continuing Review April 2007 (Protocol Version Date 03/05/07)
- 03/28/07: CIRB Continuing Review Reminder Notice (Protocol Version Date 03/05/07)
- Protocol Version Date 03/05/07

#### **GOG-0209**

Amendment Review (AR): Revision #10 Approval January 2008  
Documents Posted:

- CIRB Review Application (Protocol Version 01/14/08)
- Summary of CIRB Application Revisions (Protocol Version 01/14/08)
- CIRB Review Application (Protocol Version 11/05/07)
- Summary of CIRB Application Revisions (Protocol Version 11/05/07)
- 01/31/08: CIRB Review Approval January 2008 (Protocol Version 01/14/08)
- 01/10/08: CIRB Approval Pending Modification (Protocol Version 11/05/07)
- 01/09/08: CIRB Approval Pending Modification (Protocol Version 11/05/07)
- 11/05/07: Group Memo to PIO
- Protocol Version 01/14/08
- Protocol Version 01/14/08 (Track Changes)
- Protocol Version 11/05/07
- Protocol Version 11/05/07 (Track Changes)
- Appendix I-FIGO Classification
- Appendix II-QOL Cover Sheet
- Appendix III-Participation Procedure
- Informed Consent for Protocol Version 01/14/08 [per Rev 10]
- 12/07/07: CIRB Meeting Minutes

#### **ECOG-E1302**

Amendment Review (AR): Update #3 [Amendment #11] Approval November 2007  
Documents Posted:

- CIRB Application (Protocol Version 10/17/07)



- Summary of CIRB Application Revisions
- 11/15/07: CIRB Amendment #11 (Update #3) Approval November 2007
- Protocol Version 10/17/07
- Informed Consent Form for Protocol Version 10/17/07 [per Up#3-Am#11]

Amendment Review (AR): Update #2 Approval September 2007  
Documents Posted:

- CIRB Application (Protocol Version Date 09/19/07)
- Summary of CIRB Application Revisions
- 10/03/07: CIRB Update #2 Approval September 2007 (Protocol Version 09/19/07)
- Protocol Version 09/19/07
- Informed Consent Form for Protocol Version 09/19/07

#### **ECOG-E5204**

Amendment Review (AR): Update #2 Approval January 2008  
Documents Posted:

- CIRB Review Application (Protocol Version 09/11/07)
- Summary of CIRB Application Revisions (Protocol Version 09/11/07)
- 01/31/08: CIRB Update #2 Approval January 2008 (Protocol Version 09/11/07)
- 09/19/07: CTEP/PIO Memo re: Consensus Review
- 09/11/07: Group Revision Letter to CTEP
- Protocol Version 09/11/07
- Informed Consent for Protocol Version 09/11/07 [per Update #2]

#### **NCCTG-N0574**

Continuing Review (CR): January 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/29/07)
- 02/04/08: CIRB Continuing Review Approval January 2008 Protocol Version 08/29/07
- 12/11/07: CIRB Continuing Review Notice
- Protocol Version 08/29/07
- Informed Consent for Protocol Version 08/29/07 [per Jan 2008 CR]
- Sept 2007: Status Report
- 09/25/07: DMC/SAE Report



### **NSABP-B-33**

Continuing Review (CR): February 2008

Documents Posted:

- CIRB Continuing Review Application
- 02/11/08: CIRB Continuing Review Approval February 2008 Protocol Version 03/26/07
- 01/10/08: Group Cover Letter
- 12/11/07: CIRB Continuing Review Notice
- Protocol Version 03/26/07
- 01/29/08: Primary Reviewer Comments
- Study Summary

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

Continuing Review (CR): February 2008

Documents Posted:

- 02/11/08: CIRB Continuing Review Approval February 2008 (Protocol Version 03/13/07)
- 01/18/08: Group Cover Letter
- 11/26/07: CIRB Continuing Review Notice
- Protocol Version 03/13/07
- Informed Consent for Protocol Version 03/13/07 (per CR Feb 08)
- 10/12/07: DMC Minutes
- 04/13/07: DMC Minutes
- Progress Report

### **NSABP-B-40**

Continuing Review (CR): December 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/30/07)
- 01/07/08: CIRB Continuing Review Approval December 2007 (Protocol Version 05/30/07)
- 11/21/07: Group Review Letter
- Protocol Version 05/30/07
- Informed Consent for Protocol Version 05/30/07 [per Dec 07 CR]
- 12/17/07: CIRB Meeting Minutes
- 10/12/07: DMC Minutes
- 04/13/07: DMC Minutes
- Progress Report 2006



#### **RTOG-0521**

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/27/07)
- 02/01/08: CIRB Continuing Review Approval January 2008 Protocol Version 04/27/07
- 11/26/07: CIRB Continuing Review Notice
- Protocol Version 04/27/07
- Informed Consent for Protocol Version 04/27/07 [per Jan 08 CR]
- Informed Consent (Tissue) for Protocol Version 04/27/07 [per Jan 08 CR]
- 01/04/08: Primary Reviewer Comments
- 01/04/08: CIRB Meeting Minutes
- 06/15/07: DMC Minutes
- Status Summary-June 2007

#### **RTOG-0522**

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/14/07)
- 02/04/08: CIRB Continuing Review Approval January 2008 Protocol Version 02/14/07
- 11/26/07: CIRB Continuing Review Notice
- Protocol Version 02/14/07
- Informed Consent for Protocol Version 02/14/07 [per Jan 2008 CR]
- 01/04/08: Primary Reviewer Comments
- 01/04/08: CIRB Meeting Minutes
- 06/15/07: DMC Minutes
- June 2007: Study Summary
- Summary of Changes

#### **SWOG-S0518**

Continuing Review (CR): February 2008

Documents Posted:

- CIRB Continuing Review Application
- 02/11/08: CIRB Continuing Review Approval February 2008 Protocol Version 09/04/07
- 12/11/07: CIRB Continuing Review Notice
- Protocol Version 09/04/07
- Informed Consent for Protocol Version 09/04/07
- 01/29/08: Primary Reviewer Comments



## **SWOG-S0600**

Amendment Review (AR): Amendment 1 Approval December 2007

Documents Posted:

- CIRB Review Application (Protocol Version 09/27/07)
- Summary of CIRB Application Revisions
- 01/09/08: CIRB Review Approval December 2007 (Protocol Version 09/27/07)
- Protocol Version 09/27/07
- Informed Consent for Protocol Version 09/27/07 [per Am 1]
- 12/07/07: CIRB Meeting Minutes

## **Serious Adverse Events**

**Study: NSABP-B-40**

**SAE Posted: 246935(2) / 240958(2) / 248340 / 248750(2) / 247191(1) / 247544(1) / 247765(1) / 248750 / 248756(1) / 249106 / AU200611001243(1) / CN200707006129 / 246769 / 232048(2) / 246934 / 245872(1) / 216549(2) / 238168(4) / 243768(1)**

**Study: NSABP B-38**

**SAE Posted: AU200611001243(1) / CN200707006129**

**Study: NSABP-C-08**

**SAE Posted: 246935(2) / 240958(2) / 248340 / 248750(2) / 1476709 / 247191(1) / 247544(1) / 247765(1) / 248750 / 248756(1) / 249106**

**Study: NSABP B-34**

**SAE Posted: FR-2007-041732 Safety Update #61 / GB-2007-040750 Safety Update #60 / DE-2007-027975 Safety Update #52 / AU-2007-027436 Safety Update #51 / GB-2007-028574 Safety Update #53**

**Study: RTOG 0320**

**SAE Posted: 2007SP020357 / 2007SP018230(1) / 2007SP020357(2) / 2007SP018230(2) / 2007SP012156(3) / 2007SP023870 / 2007SP023974 / 2007SP012156(4)**

**Study: RTOG 0525**



**SAE Posted: 2007SP020357 / 2007SP018230(1) / 2007SP020357(3) /  
2007SP018230(2) / 2007SP012156(3) / 2007SP023870 / 2007SP023974 /  
2007SP012156(4)**

**Study: RTOG 0522**

**SAE Posted: 07-02-12974 / 07-02-12635(1) / 07-02-12992 / 07-02-13172 / 07-  
02-13037 / 07-02-13307 / 07-02-13307(1) / DDL#252 07-02-12410**

**Study: ECOG E2805**

**SAE Posted: 1982942(1) / 1982942(2)**

**Study: ECOG 2499**

**SAE Posted: 1893079**

**Study: ECOG E1900**

**SAE Posted: 1893079**

**Study: ECOG E1805**

**SAE Posted: 1893079**

**Study: ECOG E1A05**

**SAE Posted: 1655103**

**Study: CALGB 100104**

**SAE Posted: 1655103**

**Study: SWOG S0232**

**SAE Posted: 1655103**

**Study: SWOG S0307**

**SAE Posted: DE-2007-027975 Safety Update #52 /  
AU-2007-027436 Safety Update #51 / GB-2007-028574 Safety Update #53**

**Study: SWOG S0205**

**SAE Posted: DDL#252 07-02-12410**



**Study: SWOG 0600**  
**SAE Posted: 07-02-12974 / DDL#252 07-02-12410**

**Study: SWOG S0106**  
**SAE Posted: 1893079**

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

### **CALGB-90206**

Amendment Review (AR): Update #9 Approval October 2007  
Documents Posted:

- 01/21/08: ERRATUM: CIRB Approval Expiration Date Update #9 Review

Correction: The CALGB 90206 Update #9 approval letter dated October 31, 2007 contains an error in the expiration date. The date should read "September 5, 2008" instead of "September 6, 2008."

### **COG-ACCRN07**

Initial Review 2007 Approval  
Documents Posted:

- Informed Consent for Protocol Version Date 09/19/07 - Patient Consent
- Informed Consent for Protocol Version Date 09/19/07 - Parental Consent
- Assent Form for Protocol Version Date 09/19/07
- Information Sheet for ACCRN07 Protocol Version Date 09/19/07
- Permission Forms for ACCRN07 Protocol Version Date 09/19/07

Correction: The posted documents were originally contained within one file labeled Informed Consent for Protocol Version Date 09/19/07. These documents were separated and reposted on the NCI website. The content and approval dates have not changed.

### **RTOG-0525**

Amendment Review (AR): Amendment 3 Approval November 2007  
Documents Posted:

- 02/07/08: ERRATUM: CIRB Expiration Date in Approval Letter



Correction: The RTOG 0525 Amendment #3 approval letter dated December 3, 2007 contains an error in the expiration date. The date should read "August 2, 2008" instead of "September 6, 2008."

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).