



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

**October 31, 2007**

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. **\*\***



## **Other Activity Posted:**

### **CALGB-90401**

Amendment Review (AR) Update #3

Documents Posted:

- 10/15/07: Change Memo
- 09/15/07: Change Memo (Track Changes)
- 09/15/07: Change Memo
- CIRB Application Version 07/30/07
- Summary of CIRB Application Revisions
- 10/04/07: CIRB Approval to Update # 3 (Protocol Version 09/19/07)
- 09/10/07: Approval Pending Modifications (Protocol Version 07/30/07)
- Protocol Version Date 09/19/07
- Protocol Version Date 07/30/07 (Track Changes)
- Protocol Version Date 07/30/07
- Informed Consent for Protocol Version 09/19/07
- 08/20/07: Minutes: Posting Update #3

### **COG – AALL03N1**

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/03/07)
- 10/16/07, CIRB Full Board Approval to Continuing Review October 2007 (Protocol Version Date 01/03/07)
- Protocol Version Date 01/03/07
- Protocol Version Date 01/03/07, Highlighted
- Informed Consent Form for Protocol Version Date 01/03/07

### **COG – AALL0433**

Continuing Review (CR): September 2007

Documents Posted:

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

### **COG – AAML0531**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/25/06)
- 10/15/07, CIRB Full Board Approval to Continuing Review September 2007 (Protocol Version Date 07/25/06)
- Informed Consent Form for Protocol Version 07/25/06



- 06/11/07, Study Progress Report
- 04/17/07, DSMC Report

#### **COG – ABTR04B1**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application Protocol Version Date 02/06/07
- 10/24/07: CIRB Approval to Continuing Review September 2007 (Protocol Version Date 02/06/07)
- 10/22/07: Group Response Letter
- 10/15/07: CIRB Approval to Pending Modification to Continuing Review September 2007 (Protocol Version Date 02/06/07)
- Protocol Version Date 02/06/07
- Informed Consent Form for Protocol Version Date 02/06/07

#### **COG – ACCL04C2**

Amendment Review (AR): Amendment #1

Documents Posted:

- 09/27/07, Primary Reviewer 1 Comments
- 09/27/07, Amendment Review Minutes

#### **COG – ACNS0423**

Amendment Review (AR): CIRB Acknowledgement Of Study Closure

Documents Posted:

- 10/29/07: Acknowledgement of Closure of Study ACNS0423
- 10/26/07: Memo re Closure of Study ACNS0423

#### **COG – ADVL0524**

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

Documents Posted:

- CIRB Application (Protocol Version Date 10/01/07)
- CIRB Application ((Protocol Version Date 06/29/07)
- 10/09/07: CIRB Approval of ADVL0524, Amendment #2
- 10/05/07: Change Letter
- 09/25/07: CIRB Approval Pending Modification, Amendment #1
- 06/29/07: Response Letter
- Protocol Version Date 10/01/07
- Protocol Version Date 10/01/07 - Highlighted Version
- Protocol Version Date 06/29/07
- Protocol Version Date 06/29/07 - Highlighted Version
- Informed Consent Form for Protocol Version 10/01/07



Continuing Review (CR): September 2007  
Documents Posted:

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

#### **COG – AHOD0521**

Amendment Review (AR): CIRB Acknowledgement of Study Reactivation  
Documents Posted:

- 10/29/07: CIRB Acknowledgement of Study Reactivation
- 10/26/07: Memo re Reactivation of Study AHOD0521
- Informed Consent Form for Protocol Version Date 05/01/07

#### **COG – ARET0231**

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

- CIRB Application (Protocol Version Date 09/26/07)
- CIRB Application (Protocol Version Date 06/25/07)
- 10/10/07: CIRB Approval of ARET0231, Amendment #1
- 09/26/07: Group Response Letter
- 09/25/07: CIRB Approval Pending Modifications Amendment #1
- 06/25/07: Change Memo
- Protocol Version Date 09/26/07
- Protocol Version Date 09/26/07 - Highlighted Version
- Protocol Version Date 06/25/07
- Protocol Version Date 06/25/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 09/26/07

#### **ECOG-E2603**

Amendment Review (AR) Addendum #9  
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version 07/05/07)
- 09/11/07: CIRB Addendum 9 Approval August 2007 (Protocol Version 07/05/07)
- Protocol Version Date 07/05/07
- Informed Consent Form for Protocol Version Date 07/05/07
- 08/20/07: NCI CIRB Minutes



### **ECOG-E2902**

Amendment Review (AR) Update #1

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 09/06/07)
- 10/11/07: CIRB Approval Letter Update 1 October 2007 Protocol Version Date 09/06/07
- Protocol Version Date 09/06/07
- Informed Consent Form for Protocol Version Date 09/06/07

### **ECOG-E4201**

Continuing Review (CR) October 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/07/07)
- 10/15/07: CIRB Continuing Review Approval October 2007 (Protocol Version 03/07/07)
- Protocol Version 03/07/07
- 10/17/05: DMC Report
- Report of Studies Dated June 2007

### **NCIC-CTG-MA.27**

Amendment Review (AR): Amendment #8

Documents Posted:

- Change Memo
- CIRB Application Version 04/27/07
- Summary of CIRB Application Revisions Version 04/27/07
- 07/31/07: CIRB Amendment #8 Approval July 2007 (Protocol Version 04/27/07)
- Protocol Version 04/27/07
- Informed Consent Form for Protocol Version 04/27/07 [Companion]

### **NCIC-CTG-MA.27**

Amendment Review (AR): Amendment #5B

Documents Posted:

- Change Memo
- CIRB Application (Protocol Version Date 05/02/07)
- Summary of CIRB Application Revisions
- 07/31/07: CIRB Amendment 5B Approval July 2007 (Protocol Version 05/02/07)
- 05/11/07: CTEP Letter



- Protocol Version Date 05/02/07 [Non-Companion]
- Informed Consent Form for Protocol Version Date 05/02/07 [Non - Companion]

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

Amendment Review (AR): Study Closure Information  
Documents Posted:

- 10/15/07: CIRB Acknowledgement of Receipt
- 10/11/07: Notification of Closure of Accrual

#### **RTOG-0126**

Amendment Review (AR): Amendment #6  
Documents Posted:

- Summary of Changes
- CIRB Application (Protocol Version Date 09/19/07)
- 10/04/07: Approval Letter
- 09/07/07: Approval Pending Modifications
- 07/10/07: Group Submission Letter
- Protocol Version 09/19/07
- Informed Consent for Protocol Version 09/19/07
- Informed Consent for Protocol Version 09/19/07 (Tissue Consent)
- 08/20/07: Minutes

#### **RTOG-0214**

Amendment Review (AR): Amendment #6  
Documents Posted:

- Summary of Changes
- 10/11/07: CIRB Approval Letter October 2007 (Protocol Version 10/01/07)
- Protocol Version Date 10/01/07
- Protocol Version Date 10/01/07, Track Changes

#### **SWOG-S0200**

Continuing Review (CR) October 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/11/07)
- 10/17/07: CIRB Continuing Review Approval October 2007 (Protocol Version 06/11/07)
- Protocol Version 06/11/07



### **SWOG-S0303**

Continuing Review (CR) October 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/12/05)
- 10/15/07: CIRB Continuing Review Approval October 2007 (Protocol Version 07/12/05)
- Protocol Version 07/12/05

### **SWOG-S0307**

Amendment Review (AR) Amendment #1

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 06/18/07)
- 10/02/07: Approval Letter
- 08/15/07: Group Response to Approval pending Modifications
- 08/02/07: Approval pending Modifications
- Protocol Version Date 06/18/07
- Protocol Submission Worksheet
- Informed Consent Form for Protocol Version Date 06/18/07
- 07/19/07: Minutes: Amendment Review

## **Serious Adverse Events**

**Study: COG-ADVL0524**  
**SAE Posted: 1402677 (1), 1491032, 1673767**

**Study: CALGB 80303**  
**SAE Posted: 240958**

**Study: CALGB-SWOG 80405**  
**SAE Posted: 240958**

**Study: CALGB 90206**  
**SAE Posted: 240958**

**Study: CALGB 90401**  
**SAE Posted: 240958**

**Study: ECOG E2100**  
**SAE Posted: 240958**

**Study: ECOG E3200**



**SAE Posted: 240958**

**Study: ECOG E4599**

**SAE Posted: 240958**

**Study: ECOG E4A03**

**SAE Posted: 1517477**

**Study: ECOG E5202**

**SAE Posted: 240958**

**Study: ECOG E5204**

**SAE Posted: 240958**

**Study: GOG-0218**

**SAE Posted: 240958**

**Study: NSABP B-34**

**SAE Posted: FR-2007-023743**

**Study: NSABP B-38**

**SAE Posted: AU200703004434 (1)**

**Study: NSABP B-40**

**SAE Posted: AU200703004434 (1)**

**Study: RTOG 0320**

**SAE Posted: 2007SP000438 (2), 2007SP007552**

**Study: RTOG 0525**

**SAE Posted: 2007SP000438 (2), 2007SP007552**

**Study: SWOG S0232**

**SAE Posted: 1517477**

**Study: SWOG S0303**

**SAE Posted: 240958**

**Study: SWOG S0307**

**SAE Posted: FR-2007-023743**



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

### **COG – AEWS0621**

Initial Review: (IR) 2006

Documents Posted:

- Protocol Version Date 02/27/07
- Protocol Version Date 02/27/07 Highlighted
- Informed Consent Form (Protocol Version Date 02/27/07)
- Erratum: AEWS0621 Protocol and Informed Consent Posting Correction

Continuing Review (CR): July 2007

Documents Posted:

- Protocol Version Date 02/27/07
- Informed Consent Form for Protocol Version Date 02/27/07 [Per July 07 Cr]
- Erratum: AEWS0621 Protocol and Informed Consent Posting Correction

Correction:

It was recently discovered that the incorrect version of the AEWS0621 protocol and informed consent document (Protocol Version Date 02/27/07) was posted on the NCI CIRB website. The version previously posted did not contain all of the Pediatric CIRB-requested changes from the initial review. The correct version of the protocol and informed consent document (Protocol Version Date 02/27/07) containing all of the requested changes has been obtained and is now posted to the website.

### **ECOG – PACCT-1**

Continuing Review: (CR) 2007

Documents Posted:

- Informed Consent Form for Protocol Version Date 07/16/07

Correction:

Page header and footer formatting corrected for page numbering.

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).