



## NCI Central IRB Study Activity Update

April 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**

#### **SWOG-S0502**

Initial Review 2006 Approval  
Documents Posted:

- Protocol Version 02/07/06
- Protocol Version 12/13/05
- Protocol Version 09/21/05
- CIRB Initial Review Application (Protocol Version 12/13/05)
- Summary of CIRB Application Revisions (Protocol Version 12/13/05)
- CIRB Initial Review Application (Protocol Version 09/21/05)
- Reviewer Comments (Protocol Version 12/13/05)
- Reviewer Comments (Protocol Version 09/21/05)
- 02/13/06: CIRB Initial Review Approval February 2006 (Protocol Version 02/07/06)
- 11/14/05: CIRB Table of Initial Review
- April 2004 - Conflict of Interest Policy

### **Pediatric CIRB Studies**

#### **COG- AAML07P1**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version Date 01/18/08
- Protocol Version Date 01/18/08 - Highlighted Version
- Protocol Version Date 08/29/07
- Protocol Version Date 08/29/07 - Highlighted
- CIRB Application (Protocol Version Date 01/18/08)
- CIRB Application (Protocol Version Date 08/29/07)
- 11/08/07: Primary Reviewer 1 Comments
- 11/08/07: Primary Reviewer 2 Comments
- 11/08/07: Primary Reviewer 3 Comments
- 11/08/07: Pharmacist Review Comments
- 02/15/08: CIRB Final Approval November 2007 (Protocol Version Date 08/29/07)



- 12/14/07: CIRB Approval Pending Modification (Protocol Version Date 08/29/07)
- 11/08/07: Minutes - Initial Review

### **Other Activity Posted:**

#### **CALGB-49907**

Amendment Review (AR) Update #15 Approval March 2007

Documents Posted:

- Informed Consent for Protocol Version 01/31/07 [closed to accrual]
- 04/11/08: CIRB Posting of Informed Consent Documents for Closed Studies

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

#### **CALGB-49907**

Continuing Review (CR) Approval February 2008

Documents Posted:

- Informed Consent for Protocol Version 01/31/07 [closed to accrual]
- 04/11/08: CIRB Posting of Informed Consent Documents for Closed Studies

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

#### **CALGB-49907**

Continuing Review (CR) Approval June 2007

Documents Posted:

- Informed Consent for Protocol Version 01/31/07 [closed to accrual]
- 04/11/08: CIRB Posting of Informed Consent Documents for Closed Studies

**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) Approval April 2008

Documents Posted:

- CIRB Continuing Review Application [Protocol Version 01/22/07]
- 04/22/08: CIRB Continuing Review Approval April 2008 (Protocol Version 01/22/07)
- 02/14/08: CIRB Continuing Review Notice
- Protocol Version 01/22/07
- Informed Consent for Protocol Version 01/22/07 [per Apr 08 CR]
- 04/21/08: Reviewer 1 Comments
- 01/15/08: DSMB Memo
- Study Summary Dated November 2007



#### **COG – AALL05B1**

Continuing Review (CR): Continuing Review April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/06/07)
- 04/28/08: CIRB Approval to Continuing Review April 2008 (Protocol Version Date 09/06/07)
- 02/13/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/06/07
- Informed Consent Form for Protocol Version Date 09/06/07
- Study Progress Report Dated 10/01/07
- 04/20/07: DSMC Report

#### **COG – AAML07P1**

Amendment Review (AR): Activation Amendment (Protocol Version Date 04/03/08)

Documents Posted:

- CIRB Application (Protocol Version Date 04/03/08)
- 04/11/08: Approval to Activation Amendment April 2008 (Protocol Version Date 04/03/08)
- Protocol Version Date 04/03/08
- Protocol Version Date 04/03/08 - Highlighted Version
- Informed Consent Form for Protocol Version Date 04/03/08 - ARM A
- Informed Consent Form for Protocol Version Date 04/03/08 - ARM B

#### **COG – ANBL0421**

Continuing Review (CR): Continuing Review April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/21/07)
- 04/28/08: CIRB Approval to Continuing Review April 2008 (Protocol Version Date 06/21/07)
- 02/13/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/21/07
- Informed Consent Form for Protocol Version Date 06/21/07
- 10/25/07: DSMC Report
- Study Progress Report Dated 10/01/07



#### **ECOG-E1302**

Amendment Review (AR): Update #3 Approval November 2007

Documents Posted:

- 10/17/07: Change Memo

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

#### **ECOG-E1302**

Amendment Review (AR): Addendum #7 Approval July 2007

Documents Posted:

- 06/06/07: Change Memo

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

#### **ECOG-E1900**

Amendment Review (AR): Patient Information Letter (Associated with Addendum #9 which is presently not activated)

Documents Posted:

- Letter to Participants of ECOG E1900

#### **ECOG-E2603**

Continuing Review (CR) Approval April 2008

Documents Posted:

- 04/04/08: 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-E2603**

Amendment Review (AR): Closure to Accrual Effective: 04/22/08

Documents Posted:

- 04/28/08: CIRB Acknowledgement of Receipt
- 03/25/08: Notification of Closure of Accrual



#### **ECOG-E5202**

Amendment Review (AR): Recruitment Material (FAQ) Approval April 2007  
Documents Posted:

- Frequently Asked Questions about E5202
- 04/23/07: CIRB Frequently Asked Questions Approval April 2007
- 04/12/07: Group Response Letter
- 04/06/07: CIRB Approval Pending Modification of Recruitment Material
- 03/19/07: Recruitment Material Minutes

#### **ECOG-E5204**

Continuing Review (CR) Approval April 2008  
Documents Posted:

- 04/04/08: CIRB Meeting Minutes

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

#### **NCCTG-N0434**

Continuing Review (CR) Approval April 2008  
Documents Posted:

- 04/04/08: CIRB Meeting Minutes

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

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

Continuing Review (CR) Approval April 2008  
Documents Posted:

- 04/04/08: CIRB Meeting Minutes

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

#### **SWOG-S0307**

Continuing Review (CR) Approval April 2008  
Documents Posted:

- 04/04/08: CIRB Meeting Minutes

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



### **SWOG-S0502**

Amendment Review (AR): Activation Amendment (Protocol Version Date 07/26/06)

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 07/26/06)
- Summary of CIRB Application Revisions
- 10/13/06: CIRB Activation Amendment Approval October 2006 (Protocol Version 07/26/06)
- 07/26/06: Group Change Memo
- Protocol Version 07/26/06
- 10/06/06: CIRB Meeting Minutes
- 10/06/06: Reviewer Comments

### **SWOG-S0502**

Amendment Review (AR): Amendment #1 (Protocol Version Date 11/26/07)

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 11/26/07)
- Summary CIRB Application Revisions
- CIRB Amendment Review Application (Protocol Version 09/04/07)
- Summary of CIRB Application Revisions
- 02/04/08: CIRB Amendment #1 Approval January 2008 (Protocol Version 11/26/07)
- 11/26/07: Group Response to CIRB
- 11/21/07: CIRB Table of Group Response
- Protocol Version 11/26/07
- Protocol Version 09/04/07
- Informed Consent for Protocol Version 11/26/07 [per Am 1]
- 01/04/08: Reviewer 1 Comments
- 10/15/07: Reviewer 1 Comments (Pharmacist)
- 10/15/07: Reviewer 2 Comments
- 01/04/08: CIRB Meeting Minutes
- 10/15/07: CIRB Meeting Minutes

### **SWOG-S0502**

Continuing Review (CR) Approval November 2006

Documents Posted:

- CIRB Continuing Review Application
- 11/15/06: CIRB Continuing Review Approval November 2006 (Protocol Version 07/26/06)
- 09/11/06: CIRB Continuing Review Notice
- Protocol Version 07/26/06



### **SWOG-S0502**

Continuing Review (CR) Approval September 2007  
Documents Posted:

- CIRB Continuing Review Application
- 09/25/07: CIRB Continuing Review Approval September 2007 (Protocol Version 07/26/06)
- Protocol Version 07/26/06

### **SWOG-0600**

Continuing Review (CR) Approval April 2008  
Documents Posted:

- 04/04/08: CIRB Meeting Minutes

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

## **Serious Adverse Events**

**Study: NCIC CTG MA.27  
AE Posted: MA27-21 FU1**

**Study: ECOG E2805  
AE Posted: 1130143 FU1**

**Study: ECOG E2902  
AE Posted: 1895396**

**Study: CALGB 80203  
AE Posted: 07-02-13172(1)**

**Study: NSABP C-08  
AE Posted: 255513(1), 254163(1), 250945(2), 254176(1), 1459647, 1435303**

**Study: NSABP B-38  
AE Posted: AU200611001243(2), US200801003965**

**Study: NSABP B-40  
AE Posted: AU200611001243(2), US200801003965, 255513(1), 254163(1), 250945(2), 254176(1), 1459647, 1435303**

**Study: RTOG 0522**



**AE Posted: 08-02-13848, 08-02-13884, 07-02-13577(1)**

**Study: NCCTG N0147**

**AE Posted: 08-02-13848, 08-02-13884, 07-02-13577(1)**

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

### **ECOG-E5103**

Amendment Review Update #2 Approval January 2008

Documents Posted:

04/16/08: CIRB Correction to Informed Consent Expiration Date

Correction:

The informed consent approved for Amendment #3 (Local #2) sent January 28, contained an error in the expiration date listed in the consent header. The date should read 05/14/2008 instead of 02/21/2009. The consent has been replaced with the appropriate header.

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

Continuing Review Approval April 2008

Documents Posted:

04/28/08: CIRB Erratum Letter for Continuing Review Approval April 2008

Protocol Version 04/27/07 [Companion]

Protocol Version 05/02/07 [Non-Companion]

Informed Consent Form for Protocol Version Date 04/27/07 [Companion]

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

Correction:

Erratum Letter clarifies the protocol versions and the informed consents for the companion and non-companion studies reviewed at the CIRB meeting on 04/04/3008.

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

Initial Review 2005 Approval

Documents Posted:

05/25/05: Initial Review Approval Pending Modification [Protocol Version 02/17/05]  
**(Document never posted)**



**RTOG-0232**

Amendment Review (AR) Amendment #4 Approval February 2008

Documents Posted:

Informed Consent for Protocol Version 01/11/08 (per Am 4)

Correction:

Replace Informed Consent with correct version.

**RTOG-0415**

Amendment Review (AR) Amendment#2 Approval December 2007

Documents Posted:

Informed Consent (Tissue) for Protocol Version 12/03/07 [per Am 2 Dec 07]

Correction:

Current Informed Consent (Tissue) document posted.

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).