



## NCI Central IRB Study Activity Update

April 16, 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. **\*\***

## **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.

### **Pediatric CIRB Studies**

#### **COG – AAML0431**

Initial Review 2006

Documents Posted:

- Protocol Version Date 06/05/06
- Protocol Version Date 06/05/06, Highlighted
- Protocol Version Date 04/21/06
- Protocol Version Date 04/21/06, Highlighted
- Protocol Version Date 11/11/05
- Informed Consent Form for Protocol Version Date 06/05/06
- CIRB Application (Protocol Version Date 06/05/06)
- CIRB Application (Protocol Version Date 04/21/06)
- CIRB Application (Protocol Version Date 11/11/05)
- 05/25/06: Primary Reviewer 1 Comments
- 05/25/06: Primary Reviewer 2 Comments
- 05/25/06: Primary Reviewer 3 Comments
- 05/25/06: Pharmacist Comments
- 01/26/06: Primary Reviewer 1 Comments
- 01/26/06: Primary Reviewer 2 Comments
- 01/26/06: Primary Reviewer 3 Comments
- 06/07/06: CIRB Final Approval
- 06/07/06: CIRB Final Approval: Local Chair
- 06/05/06: CIRB Response Letter
- 06/05/06: CIRB Approval Pending Modification to Group Response Review
- 04/26/06: CIRB Response Letter
- 02/06/06: CIRB Table of Initial Review Letter
- 11/11/05: Change Memo
- 05/25/06: Meeting Minutes
- 01/26/06: Initial Review Meeting Minutes

### **Other Activity Posted:**

#### **ACOSOG – Z1031**

Amendment Review (AR): Amendment #4 (Protocol Version Date 12/18/06)

Documents Posted:

- 02/02/07: Approval Letter (Updated 04/11/07)



### **CALGB – SWOG C80405**

Continuing Review (CR) February 2007 Approval  
Documents Posted:

- Study Summary

### **COG – AAML0431**

Continuing Review (CR) April 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/05/06)
- 04/09/07: Approval Letter
- 01/02/07: Continuing Review Reminder Notice
- Protocol Version Date 06/05/06
- Protocol Version Date 06/05/06, Highlighted
- Informed Consent Form for Protocol Version Date 06/05/06 [per Apr 07 CR]

### **COG – AREN0532**

Amendment Review (AR): Amendment #1 (Protocol Version Date 02/23/07)  
Documents Posted:

- Protocol Version Date 02/23/07
- Informed Consent Form for Protocol Version Date 02/23/07:  
Chemotherapy Arm
- Informed Consent Form for Protocol Version Date 02/23/07:  
Observation Arm

### **COG – ARST0431**

Amendment Review (AR): Amendment #2 (Protocol Version Date 02/23/07)  
Documents Posted:

- CIRB Application (Protocol Version Date 11/02/06)
- CIRB Application (Protocol Version Date 02/23/07)
- 03/12/07: Approval Letter
- 02/23/07: Approval Pending Modification (Protocol Version Date 02/23/07)
- 01/14/07: Protocol Changes Letter
- 02/23/07: COG Response Letter
- 11/02/06: Protocol Changes Letter (Protocol Version Date 11/02/06)
- Protocol Version Date 02/23/07
- Protocol Version Date 02/23/07, Track Changes
- Protocol Version Date 11/02/06
- Protocol Version Date 11/02/06, Highlighted
- Informed Consent Form for Protocol Version Date 02/23/07



#### **ECOG – E2805**

Amendment Review (AR): Amendment #3 (Protocol Version Date 11/22/06)  
Documents Posted:

- CIRB Application (Protocol Version Date 11/22/06)
- CIRB Application Revision Summary (Protocol Version Date 11/22/06)
- 03/01/07: Approval Letter
- Protocol Version Date 11/22/06
- Informed Consent Form for Protocol Version Date 11/22/06

#### **ECOG – E3805**

Amendment Review (AR): Update #2 (Protocol Version Date 01/02/07)  
Documents Posted:

- CIRB Application (Protocol Version Date 01/02/07)
- CIRB Application Revision Summary (Protocol Version Date 01/02/07)
- 03/07/07: Approval Letter
- Protocol Version Date 01/02/07
- Informed Consent Form for Protocol Version Date 01/02/07

#### **NCCTG – N0574**

Continuing Review (CR) April 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/14/06)
- 04/13/07: Approval Letter
- Protocol Version Date 06/14/06
- Informed Consent Form for Protocol Version Date 06/14/06 [per Apr 07 CR]

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

Continuing Review (CR) April 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/30/04)
- 04/10/07: Approval Letter
- 02/01/07: Continuing Review Notice Letter
- Protocol Version Date 03/30/04 [per Apr 07 CR]

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

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/30/06)
- 03/28/07: Approval Letter
- 02/08/07: Continuing Review Cover Letter



- Protocol Version Date 03/30/06
- Informed Consent Form for Protocol Version Date 03/30/06

#### **RTOG – 0214**

Amendment Review (AR): Amendment #5 (Protocol Version Date 01/24/07)  
Documents Posted:

- Summary of Changes: Study
- CIRB Application (Protocol Version Date 01/24/07)
- Summary of CIRB Application Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 01/24/07
- Protocol Version Date 01/24/07, Tracked Changes
- Informed Consent Form for Protocol Version Date 01/24/07

#### **SWOG – S0226**

Amendment Review (AR): Revision #2 (Protocol Version Date 11/13/06)  
Documents Posted:

- CIRB Application (Protocol Version Date 11/13/06)
- 03/16/07: Revision #2 Approval Letter
- 02/05/07: CIRB Table of Revision #2
- 01/24/07: CIRB Table of Revision #2: Study Chair
- Protocol Version Date 11/13/06
- Informed Consent Form for Protocol Version Date 11/13/06
- 12/18/06: Primary Reviewer 1 Comments

#### **SWOG – S0334**

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/11/06)
- 04/04/07: Approval Letter
- 02/01/07: CIRB Continuing Review Reminder Notice
- Protocol Version Date 07/11/06
- Informed Consent Form for Protocol Version Date 07/11/06 [per Mar 07 CR]
- Study Summary

#### **SWOG – S0421**

Amendment Review (AR): Amendment #1 (Protocol Version Date 02/01/07)  
Documents Posted:

- CIRB Application (Protocol Version Date 02/01/07)
- CIRB Application Revision Summary
- 03/14/07: Approval Letter



- Protocol Version Date 02/01/07
- Informed Consent Form for Protocol Version Date 02/01/07

## **Serious Adverse Events**

**Study: CALGB-80303  
SAE Posted: 233053 (1)**

**Study: CALGB-90206  
SAE Posted: 233053 (1)**

**Study: CALGB-90401  
SAE Posted: 233053 (1)**

**Study: CALGB-SWOG-90401  
SAE Posted: 233053 (1)**

**Study: ECOG E2100  
SAE Posted: 233053 (1)**

**Study: ECOG E3200  
SAE Posted: 233053 (1)  
Study: ECOG E4599  
SAE Posted: 233053 (1)**

**Study: ECOG E5202  
SAE Posted: 233053 (1)**

**Study: ECOG E5204  
SAE Posted: 233053 (1)**

**Study: GOG-0218  
SAE Posted: 233053 (1)**

**Study: NSABP B-34  
SAE Posted: Safety Update #34 (FU 2) / GB-2007-027512, Safety Update #34 (FU 3), Safety Update #39 (FU 1) / GB-2006-040116, Safety Update # 43 / GB-2007-005298, Safety Update # 43 (FU 1), Safety Update # 44**

**Study: NSABP B-38  
SAE Posted: DE200701005615**

**Study: NSABP B-40  
SAE Posted: 231325 (2), 234306 (1), 235241, 235298, DE200701005615**

**Study: NSABP C-08**



**SAE Posted: 231325 (2), 233053 (1)**

**Study: RTOG 0320**

**SAE Posted: 2006SP004547 (3)**

**Study: RTOG 0522**

**SAE Posted: DDL #243 / 07-02-11207, DDL #244 / 07-02-11206**

**Study: RTOG 0525**

**SAE Posted: 2006SP004547 (3)**

**Study: SWOG S0303**

**SAE Posted: 233053 (1)**

**Study: SWOG S0307**

**SAE Posted: GB-2006-032523, Safety Update #34 (FU 2) / GB-2007-027512, Safety Update #39 (FU 1) / GB-2006-040116, Safety Update # 43 / GB-2007-005298**

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).