



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

**May 15, 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 - ACCL05C1**

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 10/23/06, Group Response
- Protocol Version Date 10/23/06, Highlighted - Group Response
- Protocol Version Date 10/13/06, Group Response
- Protocol Version Date 10/13/06, Highlighted - Group Response
- Protocol Version Date 09/05/06, Group Response
- Protocol Version Date 09/05/06, Highlighted - Group Response
- Protocol Version Date 04/05/06
- Informed Consent for Protocol Version Date 10/23/06, Group Response
- CIRB Application (Protocol Version Date 10/13/06)
- CIRB Application (Protocol Version Date 09/05/06)
- CIRB Application (Protocol Version Date 04/05/06)
- 09/05/06: Primary Reviewer 1 Comments
- 09/05/06: Primary Reviewer 2 Comments
- 09/05/06: Primary Reviewer 3 Comments
- 05/07/07: Study Activation Memo
- 10/23/06: Group Response Letter
- 10/20/06: CIRB Approval Pending Modification
- 10/13/06: Group Response Letter
- 10/06/06: CIRB Approval Pending Modification
- 09/05/06: Group Response Letter
- 06/29/06: CIRB Approval Pending Modification
- 09/28/06: Meeting Minutes
- 06/22/06: Meeting Minutes

#### **COG-AEWS0621**

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 02/27/07
- Protocol Version Date 02/27/07, Highlighted
- Protocol Version Date 01/08/07
- Protocol Version Date 01/08/07, Highlighted
- Protocol Version Date 11/06/06
- Protocol Version Date 11/06/06, Highlighted
- Protocol Version Date 09/12/06
- Protocol Version Date 09/12/06, Highlighted



- Informed Consent Form for Protocol Version Date 02/27/07
- CIRB Application (Protocol Version Date 02/27/07)
- CIRB Application (Protocol Version Date 01/08/07)
- CIRB Application (Protocol Version Date 11/06/06)
- CIRB Application (Protocol Version Date 09/12/06)
- 10/12/06: Pharmacist Comments
- 10/12/06: Primary Reviewer 1 Comments
- 10/12/06: Primary Reviewer 2 Comments
- 10/12/06: Primary Reviewer 3 Comments
- 05/07/07: Study Activation Letter
- 03/12/07: CIRB Final Approval
- 02/26/07: CIRB APM of Initial Review (Protocol Version Date 01/08/07)
- 02/26/07: Group Letter for Protocol Revisions
- 12/27/06: CIRB Response to Initial Review
- 11/06/06: COG Response Letter
- 10/18/06: CIRB APM of Initial Review (Protocol Version Date 09/12/06)
- 09/12/06: Group Letter
- 01/08/06: Group Letter

### **Other Activity Posted:**

#### **COG – AAML0121**

Continuing Review (CR): May 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/21/05)
- 05/08/07: Approval Letter
- 02/01/07: Continuing Review Notice
- Protocol Version Date 10/21/05
- 10/09/06: Closure Recommendation
- 09/05/06: Study Progress Report

#### **COG - ACCL05C1**

Amendment Review (AR): Update #1 (Protocol Version Date 01/30/07)

Documents Posted:

- CIRB Application (Protocol Version Date 01/30/07)
- 02/20/07: CIRB Approval (Protocol Version Date 01/30/07)
- 01/30/07: Change Memo
- Protocol Version Date 01/30/07
- Protocol Version Date 01/30/07, Highlighted
- Informed Consent for Protocol Version 01/30/07



Continuing Review (CR): February 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/23/06)
- 03/12/07: CIRB Approval Letter
- 02/01/07: Continuing Review Reminder Notice (Protocol Version Date 10/23/06)
- Protocol Version Date 10/23/06
- Informed Consent for Protocol Version Date 10/23/06

#### **COG – AHOD04B1**

Continuing Review (CR): February 2007  
Documents Posted:

- CIRB Application (Protocol Version Date 04/30/07)
- 05/11/07: Approval Letter
- 04/30/07: Annual Review Memo
- 04/24/07: Approval Pending Modification (Protocol Version Date 09/21/06)
- 02/01/07: Continuing Review Notice Letter
- Protocol Version Date 04/30/07
- Protocol Version Date 04/30/07, Highlighted
- Informed Consent Form for Protocol Version Date 04/30/07

#### **COG-D9902**

Amendment Review (AR): Update #9 (Protocol Version Date 04/02/07)  
Documents Posted:

- CIRB Application (Protocol Version Date 04/02/07)
- CIRB Application (Protocol Version Date 02/02/07)
- 04/20/07: Approval Letter
- 04/02/07: Study Chair Response to CIRB APM
- 03/28/07: Approval Pending Modification Letter
- 02/02/07: Change Letter
- Protocol Version Date 04/02/07
- Protocol Version Date 04/02/07, Highlighted Changes
- Protocol Version Date 02/02/07
- Protocol Version Date 02/02/07, Highlighted Changes
- Informed Consent for Protocol Version 04/02/07

#### **ECOG – E1302**

Continuing Review (CR): April 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/29/06)
- 05/11/07: Approval Letter



- 02/01/07: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/29/06
- Informed Consent Form for Protocol Version Date 11/29/06 [per Apr 07 CR]
- 09/08/06: DMC Minutes
- Toxicity Summary
- Study Summary

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

Continuing Review (CR) May 2007 Approval  
Documents Posted:

- Continuing Review 2007: Continuing Review Application
- 05/04/07, Approval (Protocol Version Date 10/27/05)
- 04/10/07, Group Response to Approval Pending Modification Letter
- 04/06/07, Approval Pending Modifications (Protocol Version Date 10/27/05)
- Protocol Version Date 10/27/05
- Main Informed Consent Document for Protocol Version 10/27/05 [per May 2007 CR]
- Tissue Sample Informed Consent Document for Protocol Version Date 10/27/05 [per May 2007 CR]
- Informed Consent Document Addendum 1 for Protocol Version Date 10/27/05 [per May 2007 CR]
- 04/07/06, DMC Minutes
- 10/20/06, DMC Minutes

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

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- 10/20/06: DMC Minutes
- 04/07/06: DMC Minutes
- Progress Report

#### **SWOG S0500**

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application 11/21/06
- 03/14/07: CIRB Approval (Protocol Version Date 11/21/06)
- 02/01/07: Continuing Review Notification
- Protocol Version Date 11/21/06
- Informed Consent Document for Protocol Version Date 11/21/06



## **Serious Adverse Events**

**Study: ECOG E2603**  
**SAE Posted: 1007443, 1333296, 1447378**

**Study: ECOG E2805**  
**SAE Posted: 1007443, 1333296, 1447378**

**Study: NSABP B-38**  
**SAE Posted: DE200702000654, DE200702002598**

**Study: NSABP B-40**  
**SAE Posted: DE200702000654, DE200702002598**

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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).