



## NCI Central IRB Study Activity Update

March 30, 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 – ACNS0332**

Initial Review 2006

Documents Posted:

- Protocol Version 03/07/06
- Protocol Version 09/12/06, Highlighted
- Protocol Version 06/28/06
- Protocol Version 06/28/06, Highlighted
- Protocol Version 09/12/06
- Informed Consent Protocol Version 09/12/06
- Revised CIRB Application (for Protocol Version 03/07/06)
- CIRB Application Version 09/12/06
- CIRB Application Version 06/28/06
- 04/19/06: Primary Reviewer 1 Comments
- 04/20/06: Primary Reviewer 2 Comments
- 04/21/06: Primary Reviewer 3 Comments
- 03/07/06: Change Memo
- 03/20/06: Notice of Protocol Approved on Hold
- 09/01/06: CIRB Final Approval Letter
- 07/03/06: CIRB Approval Pending Modification to Initial Review
- 05/05/06: Initial Review Tabled
- 09/13/06: Response Letter
- 06/28/06: Response Letter
- 04/24/06 Minutes: Discussion Initial Review
- 07/27/06 Minutes: Discussion Group Response to Tabled Action

#### **COG – AALL0433**

Initial Review 2006

Documents Posted:

- Protocol Version Date 06/20/06
- Protocol Version Date 06/20/06, Highlighted
- Protocol Version 12/16/2005
- Informed Consent for Protocol Version 06/20/06
- Informed Consent for Protocol Version Date 06/20/06
- CIRB Application Version 12/16/05
- 05/25/06 Primary Reviewer 1 Comments
- 05/25/06 Primary Reviewer 2 Comments



- 05/25/06 Primary Reviewer 3 Comments
- 01/26/06: Pharmacist Comments
- 01/26/06: Primary Reviewer 1 Comments
- 01/26/06: Primary Reviewer 2 Comments
- 01/26/06: Primary Reviewer 3 Comments
- 12/16/05: Review Memo
- 05/25/06 Minutes: Discussion of Group Response to Initial Review

#### **COG – AOST0331**

Initial Review 2005  
Documents Posted:

- 01/27/05: Initial Review Meeting Minutes

#### **COG – ASCT0431**

Initial Review 2006  
Documents Posted:

- Protocol Version Date 06/28/06
- Protocol Version Date 06/28/06, Highlighted
- Protocol Version Date 05/16/06
- Protocol Version Date 05/16/06, Highlighted
- Protocol Version Date 02/03/06
- CIRB Application (Protocol Version Date 06/28/06)
- CIRB Application (Protocol Version Date 05/16/06)
- CIRB Application (Protocol Version Date 02/03/06)
- 12/14/06: Primary Reviewer 1 Comments
- 06/08/06: Primary Reviewer 1 Comments
- 03/23/06: Primary Reviewer 1 Comments
- 03/23/06: Primary Reviewer 2 Comments
- 03/23/06: Pharmacist Comments
- 06/19/07: CIRB Approval Pending Modification to Initial Review
- 07/11/06: CIRB Final Approval Letter
- 07/11/06: CIRB Final Approval: To Local IRB Chair(s)
- 06/28/06: COG Response to Approval Pending Modifications
- 05/16/06: COG Response Letter
- 04/11/06: CIRB Tabled Letter
- 02/03/06: Responses to Reviewer Comments
- 06/08/06: Group Response Meeting Minutes
- 03/23/06: Initial Review Meeting Minutes



## **Other Activity Posted:**

### **ACOSOG Z1031**

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

Documents Posted:

- CIRB Application Resubmission (Protocol Version Date 12/18/06)
- CIRB Application (Protocol Version Date 05/24/06)
- Summary of CIRB Application Revisions
- 02/02/07: Approval Letter
- 12/07/06: CIRB Approval Pending Modification
- Protocol Version Date 12/18/06
- Informed Consent Form for Protocol Version Date 12/18/06: Main
- Informed Consent Form for Protocol Version Date 12/18/06: Genome Atlas
- Informed Consent Form for Protocol Version Date 12/18/06: Specimen Banking
- 11/10/06: Primary Reviewer 1 Comments

### **CALGB 50303**

Amendment Review (AR): Amendment #3 (Protocol Version Date 08/22/06)

Documents Posted:

- CIRB Application (Protocol Version Date 08/22/06)
- CIRB Summary of Application Revisions (Protocol Version Date 08/22/06)
- 12/11/06: Approval Letter
- Protocol Version Date 08/22/06
- Informed Consent Form for Protocol Version Date 08/22/06
- 11/20/06: Primary Reviewer 1 Comments

Amendment Review (AR): Amendment #4 (Protocol Version Date 01/03/07)

Documents Posted:

- CIRB Application (Protocol Version Date 01/03/07)
- CIRB Summary of Application Revisions (Protocol Version Date 01/03/07)
- 02/28/07: Approval Letter
- Protocol Version Date 01/03/07
- Informed Consent Form for Protocol Version Date 01/03/07



### **COG- AALL0433**

Amendment Review (AR) Amendment #1  
Documents Posted:

- CIRB Application Version 02/23/07
- CIRB Application Version 01/20/07
- CIRB Application Version 10/24/06
- 03/12/07: Amendment Approval Letter
- 02/23/07: CIRB Approval Pending Modification Letter
- 02/23/07: Group Response Letter
- 01/20/07: Response Letter to the Chair
- 12/18/07: CIRB Approval Pending Modification Letter
- 10/24/06: Change Memo
- Protocol Version 02/23/07, Highlighted
- Protocol Version Date 02/23/07
- Protocol Version Date 01/20/07
- Protocol Version Dante 10/24/06
- Protocol Version Date 10/24/06, Highlighted
- Informed Consent Form for Protocol Version Date 02/23/07
- 11/28/06: Primary Reviewer 1 Comments

Continuing Review (CR) June 2006 Approval  
Documents Posted:

- CIRB Continuing Review Application Version 06/20/06
- 11/27/06: Continuing Review Approval (Protocol Version 06/20/06):  
Study Chair
- 09/20/06: Continuing Review Notice for November 9, 2006
- Informed Consent Protocol Version 06/20/06

### **COG – AAML0431**

Amendment Review (AR) Amendment #1  
Documents Posted:

- CIRB Application Version 02/07/07
- 03/20/07: Approval Activation Amendment for Protocol Version 02/07/07
- Protocol Version Date 02/07/07
- Protocol Version Date 02/07/07, Highlighted



### **COG- ACNS0332**

Amendment Review (AR) Amendment #1  
Documents Posted:

- CIRB Application Protocol Version 02/15/07
- 02/15/07: Activation Amendment
- 03/08/07: CIRB Amendment Approval Letter
- Protocol Version 02/15/07
- Protocol Version 02/15/07, Highlighted
- Informed Consent Protocol Version 02/15/07

### **COG- ANBL00P3**

Amendment Review (AR) Amendment #3 (This amendment is equivalent to the final version of the study for the Continuing Review for December 2006)  
Documents Posted:

- Protocol Version Date 01/31/07
- Informed Consent Form for Protocol Version Date 01/31/07: High Risk [CR06 and Amend3]
- Informed Consent Form for Protocol Version Date 01/31/07: Low Risk [CR06 and Amend3]

### **COG- ARAR0332**

Continuing Review (CR) February 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/30/06)
- 03/16/07: Approval Letter
- Protocol Version Date 08/30/06
- Protocol Version Date 08/30/06, Highlighted Changes
- Informed Consent Form for Protocol Version Date 08/30/06 [per Feb 07 CR]
- Informed Consent Form for Protocol Version Date 08/30/06: Blood Sample [per Feb 07 CR]
- Informed Consent Form for Protocol Version Date 08/30/06: p53 Testing [per Feb 07 CR]



### **COG – ASCT0431**

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

Documents Posted:

- CIRB Application (Protocol Version Date 02/23/07)
- CIRB Application (Protocol Version Date 01/11/07)
- CIRB Application (Protocol Version Date 11/07/06)
- 02/26/07: CIRB Approval Letter
- 02/23/07: CIRB Approval Pending Modification
- 02/23/07: Group Response Letter
- 01/02/07: CIRB Approval Pending Modification - Study Chair Letter
- 01/11/07: Group Response Letter
- 11/07/06: Amendment Details List
- Protocol Version Date 02/23/07
- Protocol Version Date 02/23/07, Highlighted
- Protocol Version Date 01/11/07
- Protocol Version Date 01/11/07, Highlighted
- Protocol Version Date 11/07/06
- Protocol Version Date 11/07/06, Highlighted
- Informed Consent Form for Protocol Version Date 02/23/07
- Informed Consent Form for Protocol Version Date 01/11/07
- Informed Consent Form for Protocol Version Date 06/28/06

Continuing Review (CR) March 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/11/07)
- 03/16/07: Approval Letter
- 02/01/07: Continuing Review Reminder Notice
- Protocol Version Date 01/11/07
- Protocol Version Date 01/11/07, Highlighted
- Informed Consent Form for Protocol Version Date 01/11/07

### **ECOG- E1302**

Amendment Review (AR) Amendment #6 (Protocol Version Date 11/29/06)

Documents Posted:

- CIRB Application (Protocol Version Date 11/29/06)
- Summary of CIRB Application Revisions
- 02/09/07: Approval Letter



- 11/29/06: Group Response Letter
- Protocol Version Date 11/29/06
- Informed Consent Form for Protocol Version Date 11/29/06

#### **ECOG- E3201**

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- 03/14/07: Approval Letter
- 01/02/07: Continuing Review Reminder Notice
- CIRB Continuing Review Application (Protocol Version Date 08/05/05)

#### **ECOG- E5202**

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/24/06)
- 03/14/07: Approval Letter
- Protocol Version 08/24/06
- Informed Consent Form for Protocol Version Date 08/24/06 [per March 07 CR]

#### **RTOG- 0232**

Continuing Review (CR) February 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/11/05)
- 03/01/07: Approval Letter
- Protocol Version 10/11/05
- Cost Data Informed Consent for Protocol Version 10/11/05 [per Feb 2007 CR]
- Main Informed Consent for Protocol Version 10/11/05 [per Feb 2007 CR]
- Tissue Use Informed Consent for Protocol Version 10/11/05 [per Feb 2007 CR]
- 06/16/06: DMC Minutes



### **RTOG- 0521**

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/04/06)
- 03/14/07: Approval Letter
- Protocol Version Date 10/04/06
- Informed Consent Form for Protocol Version Date 10/04/06 [per March 07 CR]
- 06/16/06: DMC Minutes

### **RTOG- 0522**

Continuing Review (CR) March 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/08/07)
- 03/14/07: Approval Letter
- Protocol Version 01/08/07
- Informed Consent Form for Protocol Version Date 01/08/07 [per March 07 CR]
- 01/17/07: DMC Minutes

## **Serious Adverse Events**

**Study: CALGB-80303**  
**SAE Posted: 230653 (1)**

**Study: CALGB- SWOG-80405**  
**SAE Posted: 230653 (1)**

**Study: CALGB-90206**  
**SAE Posted: 230653 (1)**

**Study: CALGB-90401**  
**SAE Posted: 230653 (1)**

**Study: ECOG E2100**  
**SAE Posted: 230653 (1)**

**Study: ECOG E2805**  
**SAE Posted: 1176423**



**Study: ECOG E2805**  
**SAE Posted: 2006134386**

**Study: ECOG E3200**  
**SAE Posted: 230653 (1)**

**Study: ECOG E4599**  
**SAE Posted: 230653 (1)**

**Study: ECOG E5202**  
**SAE Posted: 230653 (1)**

**Study: ECOG E2504**  
**SAE Posted: 230653 (1)**

**Study: GOG-0218**  
**SAE Posted: 230653 (1)**

**Study: NSABP B-34**  
**SAE Posted: Safety Update # 37 (FU 1) / GB-2006-03523**

**Study: NSABP C-08**  
**SAE Posted: 230653 (1)**

**Study: SWOG S0303**  
**SAE Posted: 230653 (1)**

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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).