



## NCI Central IRB Study Activity Update December 15, 2006

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@ctisinc.com](mailto:ncicirbcontact@ctisinc.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@ctisinc.com](mailto:ncicirbcontact@ctisinc.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:**

- There are no Initial Approvals to report in this Activity Update.



## **Other Activity Posted:**

### **CALGB-50303**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/27/06)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 03/27/06)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 03/27/06
- Informed Consent for Protocol Version 03/27/06 [Per Nov. 06 CR]
- Toxicity Summary Dated June 2006

### **CALGB-80101**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/07/06)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 07/07/06)
- Protocol Version 07/07/06
- Informed Consent for Protocol Version 07/07/06 [Per Nov. 06 CR]
- Abstract Dated 2006
- Toxicity Summary Dated December 2006

### **CALGB-90104**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/12/05)
- 11/20/06: CIRB Continuing Review Approval November 2006 (Protocol Version 04/12/05)
- Protocol Version 04/12/05 (includes Update #3)
- Informed Consent for Protocol Version 04/12/05 [Per Nov. 06 CR]
- Study Summary Dated June 2006

### **CALGB-90206**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/29/05)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 07/29/05)
- Protocol Version 07/29/05



- Study Summary Dated June 2006

#### **COG-AALL03B1**

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 12/11/06: CIRB Acknowledgement of Revised ALL Quick Reference Guide
- 12/08/06: Memo of Revised ALL Quick Reference Guide
- 12/11/06: CIRB Acknowledgement of Decentralization
- 12/01/06: Memo of Decentralization

#### **COG-AAML0531**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/25/06)
- 12/05/06: CIRB Continuing Review Approval November 2006 (Protocol Version 07/25/06)
- 10/02/06: Continuing Review Notice for November 2006
- Protocol Version 07/25/06
- Informed Consent for Protocol Version 07/25/06 [Per Nov. 06 CR]

#### **COG-ADVL0524**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/10/06)
- 12/05/06: CIRB Continuing Review Approval November 2006 (Protocol Version 03/10/06)
- 09/20/06: Continuing Review Notice for November 2006
- Protocol Version 03/10/06
- Informed Consent for Protocol Version 03/10/06 [Per Nov. 06 CR]

#### **COG-AHOD03P1**

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 12/11/06: CIRB Acknowledgement of No Objection Letter for the use of FDG-PET Scans
- 12/08/06: Memo of No Objection Letter for the use of FDG-PET Scans



#### **COG-AHOD0431**

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 12/11/06: CIRB Acknowledgement of No Objection Letter for the use of FDG-PET Scans
- 12/08/06: Memo of No Objection Letter for the use of FDG-PET Scans

#### **COG-AREN03B2**

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 12/11/06: CIRB Acknowledgement of Revised Specimen Transmittal Form and eRDEs Screen
- 12/01/06: Memo of Revised Specimen Transmittal Form and eRDEs Screen

#### **ECOG-E1Y03**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 12/15/05)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 12/15/05)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 12/15/05
- Informed Consent for Protocol Version 12/15/05 [Per Nov. 06 CR]

#### **ECOG-E1301**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/03/04)
- 12/11/06: CIRB Continuing Review Approval November 2006 (Protocol Version 09/03/04)
- 10/03/06: Continuing Review Notice for November 2006
- Protocol Version 09/03/04 (Per Addendum #4)
- 11/02/04: DMC Report
- Report of Studies Dated June 2005



### **ECOG-E3200**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/02/06)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 02/02/06)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 02/02/06
- 11/02/04: DMC Report
- 10/19/06: ADDERS Listing
- Report of Studies Dated November 2004

### **ECOG-E4A03**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/26/06)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 04/26/06)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 04/26/06
- Informed Consent for Protocol Version 04/26/06 [Per Nov. 06 CR]
- 04/28/06: DMC Report
- Report of Studies Dated November 2005
- 12/28/05: Revised Case Report Forms

### **ECOG-E4402**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/28/06)
- 09/11/06: Continuing Review Notice for November 2006
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 02/25/05)
- Protocol Version 02/25/05 (per Addendum #2)
- Informed Consent for Protocol Version 02/25/05 [Per Nov. 06 CR]
- 04/28/06: DMC Report
- Report of Studies Dated June 2006



### **ECOG-E4599**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/03/05)
- 11/29/06: CIRB Approval to Continuing Review Approval November 2006 (Protocol Version 08/03/05)
- Protocol Version 08/03/05
- Technical Report Dated September 2006

### **ECOG-PACCT-1**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/23/06)
- 12/12/06: CIRB Continuing Review Approval November 2006 (Protocol Version 08/23/06)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 08/23/06
- Informed Consent for Protocol Version 08/23/06 [Per Nov. 06 CR]

### **GOG-0209**

Amendment Review: Revision #8 (Protocol Version 09/21/06)

Documents Posted:

- CIRB Application Version 09/21/06
- Summary of CIRB Application Revisions Version 09/21/06
- 10/05/06: CIRB Revision #8 Approval (Protocol Version 09/21/06)
- 09/21/06: GOG Response to Approval Pending Modification (Protocol Version 07/26/06)
- 09/11/06: Approval Pending Modification (Protocol Version 07/26/06)
- Protocol Version 09/21/06
- Informed Consent for Protocol Version 09/21/06
- 09/01/06: Primary Reviewer 1 Comments
- 09/01/06, Minutes: Revision #8 Review

### **NSABP-C-08**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/21/06)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 04/21/06)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 04/21/06



- Informed Consent for Protocol Version 04/21/06 [Per Nov. 06 CR]
- Report of Studies Dated February 2006
- 10/11/06: Cover Letter
- 04/07/06: DMC Report

#### **RTOG-0129**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/31/05)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 01/31/05)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 01/31/05 (includes Revision #5)
- Study Progress Report Dated June 2006
- 06/16/06: DMC Report

#### **RTOG-0320**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/06/06)
- 12/11/06: CIRB Continuing Review Approval November 2006 (Protocol Version 04/06/06)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 04/06/06
- Informed Consent for Protocol Version 04/06/06 [Per Nov. 06 CR]
- Report of Studies Dated June 2006
- 06/16/06: DMC Report

#### **RTOG-0412-SWOG-0332**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/16/06)
- 11/29/06: CIRB Continuing Review Approval November 2006 (Protocol Version 02/16/06)
- Protocol Version 02/16/06
- Informed Consent for Protocol Version 02/16/06 [Per Nov. 06 CR]
- Study Progress Report Dated June 2006
- 06/16/06: DMC Report



## **SWOG-S0012**

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/14/04)
- 12/12/06: CIRB Continuing Review Approval November 2006 (Protocol Version 05/14/04)
- 09/11/06: Continuing Review Notice for November 2006
- Protocol Version 05/14/04 (Includes Revision #5)
- Report of Studies Dated October 2006
- 05/19/06: DMC Report

### **Serious Adverse Events**

**Study: None**

**SAE Posted: There are no SAEs to report in this Activity Update.**

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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@ctisinc.com](mailto:ncicirbcontact@ctisinc.com).