



## NCI Central IRB Study Activity Update November 30, 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-10201**

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

Documents Posted:

- 10/20/06: CIRB Acknowledgement of Notice of Accrual Closure
- 10/05/06: Memo of Notice of Accrual Closure

### **CALGB-40302**

Continuing Review (CR) March 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 12/01/05)
- 03/20/06: CIRB Continuing Review Approval March 2006 (Protocol Version 12/01/05): Study Chair
- 03/17/06: CIRB Continuing Review Approval March 2006 (Protocol Version 12/01/05): Local IRB
- 03/07/06: Continuing Review Notice for March 2006
- Protocol Version 12/01/05
- Informed Consent for Protocol Version 12/01/05 [Per March 06 CR]

### **CALGB-70301**

Amendment Review: Update #2 (Protocol Version 07/07/06)

Documents Posted:

- 09/15/06: Change Memo
- Quality of Life Questionnaire [QLQ-C30]
- CIRB Application Version 07/07/06
- Summary of CIRB Application Revisions Version 07/07/06
- 08/25/06: CIRB Update #2 Approval (Protocol Version 07/07/06)
- Protocol Version 07/07/06
- Informed Consent for Protocol Version 07/07/06

### **CALGB-80203**

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06, Minutes: Continuing Review October 2006



### **CALGB-80303**

Amendment Review: Update #6 (Protocol Version 06/20/06)

Documents Posted:

- 09/15/06: Change Memo
- CIRB Application Version 06/20/06
- Summary of CIRB Application Revisions Version 06/20/06
- 09/27/06: CIRB Update #6 Approval (Protocol Version 06/20/06)
- Protocol Version 06/20/06
- Informed Consent for Protocol Version 06/20/06

### **CALGB-90202**

Amendment Review: Update #5 (Protocol Version 08/29/06)

Documents Posted:

- 10/15/06: Change Memo
- CIRB Application Version 08/29/06
- Summary of CIRB Application Revisions Version 08/29/06
- 10/05/06: CIRB Update #5 Approval (Protocol Version 08/29/06)
- Protocol Version 08/29/06
- Informed Consent for Protocol Version 08/29/06

### **COG-AALL0331**

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

Documents Posted:

- 11/24/06: Acknowledgement of CRF and eRDE Screen Revisions
- 11/17/06: Memo of CRF and eRDE Screen Revisions
- 11/24/06: CIRB Acknowledgement of Revised Adverse Event Reporting/Toxicity Forms
- 11/24/06: CIRB Acknowledgement of Errors found in Standard Risk - Average consent
- 11/10/06: Memo of Revised Adverse Event Reporting/Toxicity Forms
- 11/10/06: Memo of Errors found in Standard Risk - Average consent

### **COG-AALL03B1**

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

Documents Posted:

- 11/24/06: CIRB Acknowledgement of Revised Risk Group Assignment CRF and eRDES Screen
- 11/17/06: Memo of Revised Risk Group Assignment CRF and eRDES Screen



- 11/24/06: CIRB Acknowledgement of Revised help text on Eligibility and Institutional Diagnostic Specimen Testing CRFs...
- 11/24/06: CIRB Acknowledgement of Decentralized Cytogenetic Stratification Timeline for AALL03B1
- 11/10/06: Memo of Revised help text on Eligibility and Institutional Diagnostic Specimen Testing CRFs and eRDEs screens
- 11/10/06: Memo of Decentralized Cytogenetic Stratification Timeline for AALL03B1

#### **COG-AREN03B2**

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

Documents Posted:

- 11/24/06: CIRB Acknowledgement of Revised CRFs
- 11/17/06: Memo of Revised CRFs

#### **COG-ARET0331**

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/17/06)
- 11/15/06: CIRB Continuing Review Approval October 2006 (Protocol Version 04/17/06)
- 10/23/06: CIRB Continuing Review Tabled Letter (Protocol Version 04/17/06)
- 07/21/06: Continuing Review Notice for October 2006
- Protocol Version 04/17/06
- Informed Consent for Protocol Version 04/17/06 [Per Oct. 06 CR]
- Study Progress Report Dated 09/05/06

#### **COG-ARET0332**

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

Documents Posted:

- 11/24/06: CIRB Acknowledgement of Health Canada No Objection Letter for Amendment #1A ARET0332
- 11/17/06: Memo of Health Canada No Objection Letter for Amendment #1A ARET0332



#### **GOG-0204**

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Documents Posted:

- 09/18/06, Minutes: Continuing Review September 2006

#### **GOG-0209**

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Documents Posted:

- 09/18/06, Minutes: Continuing Review September 2006

#### **RTOG-0521**

Amendment Review: Amendment #1 (Protocol Version 10/04/06)

Documents Posted:

- 10/04/06: Change Memo
- 10/11/06: CIRB Amendment #1 Approval (Protocol Version 10/04/06)
- 10/04/06: RTOG Response to Approval Pending Modification (Protocol Version 10/04/06)
- 09/06/06: Approval Pending Modification (Protocol Version 07/25/06)
- 07/25/06: RTOG Response to Approval Pending Modification (Protocol Version 07/25/06)
- 05/24/06: Approval Pending Modification (Protocol Version 04/12/06)
- Protocol Version 10/04/06
- Informed Consent for Protocol Version 10/04/06

#### **SWOG-S0221**

Amendment Review: Amendment #4 (Protocol Version 09/15/06)

Documents Posted:

- CIRB Application Version 09/15/06
- Summary of CIRB Application Revisions Version 09/15/06
- 11/08/06: CIRB Amendment #4 Approval (Protocol Version 09/15/06)
- Protocol Version 09/15/06
- Informed Consent for Protocol Version 09/15/06

#### **SWOG-S0232**

Amendment Review: Revision #1 (Protocol Version 10/03/06)

Documents Posted:

- CIRB Application Version 10/03/06
- Summary of CIRB Application Revisions Version 10/03/06



- 11/08/06: CIRB Revision #1 Approval (Protocol Version 10/03/06)
- Protocol Version 10/03/06
- Informed Consent for Protocol Version 10/03/06

### **SWOG-S0307**

Amendment Review: Revision #2 (Protocol Version 09/25/06)  
Documents Posted:

- CIRB Application Version 09/25/06
- Summary of CIRB Application Revisions Version 09/25/06
- 10/24/06: CIRB Revision #2 Approval (Protocol Version 09/25/06)
- Protocol Version 09/25/06
- Informed Consent for Protocol Version 09/25/06

### **Serious Adverse Events**

**Study: CALGB 10201**  
**SAE Posted: 1099248**

**Study: CALGB 80203**  
**SAE Posted: DDL 231 / 06-02-07687**

**Study: CALGB-SWOG 80405**  
**SAE Posted: DDL 231 / 06-02-07687**

**Study: ECOG E2100**  
**SAE Posted: 229923**

**Study: ECOG E3200**  
**SAE Posted: 229923**

**Study: ECOG 4599**  
**SAE Posted: 229923**

**Study: ECOG 5202**  
**SAE Posted: 229923**

**Study: ECOG 5204**  
**SAE Posted: 229923**

**Study: GOG 0219**  
**SAE Posted: 1412169**

**Study: NSABP B-34**  
**SAEs Posted: Safety Update #27 FU 1, Safety Update #34**



**Study: NSABP B-38**

**SAEs Posted: Safety Update #83 FU 1, Safety Update #99, Safety Update #91, Safety Update #79 FU 2, Safety Update #98, DE200608006737**

**Study: RTOG 0320**

**SAEs Posted: 2006SP000744 FU 2, 2006-07-1249 FU 2, 2006-08-0388 (2), 2005-11-1372 (2), 2005-11-1372 (3), 2006SP002722, 2006SP004704**

**Study: RTOG 0522**

**SAEs Posted: DDL 230 (1) / 06-02-10236 (1), DDL 233 / 06-02-10517, DDL 234 / 06-02-10504, DDL 235 / 06-02-10101, DDL 236 / 05-02-06051, DDL 237 / 06-02-10133**

**Study: RTOG 0525**

**SAEs Posted: 2006SP000744 FU 2, 2006-07-1249 FU 2, 2006-08-0388 (2), 2005-11-1372 (2), 2005-11-1372 (3), 2006SP002722, 2006SP004704**

**Study: SWOG S0200**

**SAE Posted: 20060906767 (0)**

**Study: SWOG S0205**

**SAEs Posted: DDL 230 (1) / 06-02-10236 (1), DDL 231 / 06-02-07687, DDL 230 / 06-02-10236, DDL 150 (1) / 05-02-05249 (1), DDL 233 / 06-02-10517, DDL 234 / 06-02-10504, DDL 235 / 06-02-10101, DDL 236 / 05-02-06051, DDL 237 / 06-02-10133**

**Study: SWOG S0124**

**SAE Posted: 2006106955, 2006113794, 2006118188**

**Study: SWOG S0307**

**SAEs Posted: 2006003411 (1), 2006018731, 2006015298 (1), 2006015291 (1), 2006024776, 2006018731 (1), 2006026124 (1), 2006003780 (1), 2006027512**

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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).