



## NCI Central IRB Study Activity Update September 29, 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:**

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-ARAR0332**

Initial Review Approval  
Documents Posted:

- Protocol Version 12/13/05
- Protocol Version 12/13/05, Highlighted Changes
- Protocol Version 08/09/05
- Protocol Version 08/09/05, Highlighted Changes
- Protocol Version 05/24/05
- Protocol Version 05/24/05, Highlighted Changes
- Protocol Version 02/15/05
- Informed Consent for Protocol Version 12/13/05
- Informed Consent for Protocol Version 12/13/05: p53 Testing
- Informed Consent for Protocol Version 12/13/05: Blood Sample
- CIRB Application Version 12/13/05
- CIRB Application Version 08/09/05
- CIRB Application Version 05/24/05
- CIRB Application Version 02/15/05
- 08/25/05: Primary Reviewer 1 Comments
- 08/25/05: Primary Reviewer 2 Comments
- 08/25/05: Primary Reviewer 3 Comments
- 08/25/05: Primary Reviewer 4 Comments
- 03/10/05: Pharmacist Comments
- 12/21/05: CIRB Approval (Protocol Version 12/13/05): Study Chair
- 12/21/05: CIRB Approval (Protocol Version 12/13/05): Local IRB
- 12/13/05: COG Response to Approval Pending Modification
- 09/21/05: Approval Pending Modification (Protocol Version 08/09/05)
- 08/09/05: COG Response to Tabled Action
- 06/22/05: CIRB Tabled Letter (Protocol Version 05/24/05)
- 05/24/05: COG Response to Tabled Action
- 03/18/05: CIRB Tabled Letter (Protocol Version 02/15/05)
- 08/25/05: Initial Review Meeting Minutes

### **COG-AALL05B1**

Initial Review Approval  
Documents Posted:

- Protocol Version 03/14/06
- Protocol Version 03/14/06, Highlighted Changes
- Protocol Version 09/23/05
- Informed Consent for Protocol Version 03/14/06



- CIRB Application Version 03/14/06
- CIRB Application Version 09/23/05
- 04/24/06: Primary Reviewer 1 Comments
- 04/24/06: Primary Reviewer 2 Comments
- 04/24/06: Primary Reviewer 3 Comments
- 12/08/05: Member 1 Comments
- 12/08/05: Member 2 Comments
- 12/08/05: Primary Reviewer 1 Comments
- 12/08/05: Primary Reviewer 2 Comments
- 12/08/05: Primary Reviewer 3 Comments
- 04/21/06: Approval Pending Modification (Protocol Version 03/14/06)
- 04/28/06: CIRB Approval (Protocol Version 03/14/06): Local IRB
- 04/28/06: CIRB Approval (Protocol Version 03/14/06): Study Chair
- 03/14/06: COG Response to Approval Pending Modification
- 01/04/06: Approval Pending Modification (Protocol Version 09/23/05)
- 04/13/06: Group Response Meeting Minutes
- 12/08/05: Initial Review Meeting Minutes

### **Other Activity Posted:**

#### **ACOSOG-Z4032**

Continuing Review September 2006

Documents Posted:

- CIRB Continuing Review Application Version 04/11/05
- 07/24/06, Continuing Review Notice for September 2006
- 08/25/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 04/11/05)
- Protocol Version 04/11/05
- Informed Consent for Protocol Version 04/11/05 [Per Sep. 06 CR]
- 08/21/06: Primary Reviewer 1 Comments
- 08/21/06, Minutes: Continuing Review September 2006

#### **CALGB-90401**

Continuing Review September 2006

Documents Posted:

- CIRB Continuing Review Application Version 08/01/05
- 09/25/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 07/06/06)
- 06/21/06, Continuing Review Notice for August 2006
- Protocol Version 07/06/06
- Informed Consent for Protocol Version 07/06/06 [Per Sep. 06 CR]
- 09/18/06: Primary Reviewer 1 Comments



- June 2006, Study Summary

#### **COG-AALL0331**

Continuing Review September 2006

Documents Posted:

- CIRB Continuing Review Application Version 03/29/05
- 09/21/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 03/29/05)
- 06/27/06, Continuing Review Notice for September 2006
- Protocol Version 03/29/05
- Informed Consent for Protocol Version 03/29/05 [Per Sep. 06 CR]: Induction Therapy
- Informed Consent for Protocol Version 03/29/05 [Per Sep. 06 CR]: Standard Risk - High
- Informed Consent for Protocol Version 03/29/05 [Per Sep. 06 CR]: Standard Risk - Average
- Informed Consent for Protocol Version 03/29/05 [Per Sep. 06 CR]: Standard Risk - Low
- Study Progress Report Dated 02/23/06
- 03/27/06, DSMC Report

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

Documents Posted:

- 09/27/06: CIRB Acknowledgement of Paper Data for AALL03B1, AALL0232, and AALL0331
- 09/27/06: CIRB Acknowledgement of Revised Data Entry and Submission Schedule
- 09/22/06: Memo of Paper Data for AALL03B1, AALL0232, and AALL0331
- 09/22/06: Memo of Revised Data Entry and Submission Schedule

#### **COG-AALL03B1**

Continuing Review September 2006

Documents Posted:

- CIRB Continuing Review Application Version 03/03/05
- 06/27/06, Continuing Review Notice for September 2006
- 09/21/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 08/01/06)
- Protocol Version 08/01/06
- Informed Consent for Protocol Version 08/01/06 [Per Sep. 06 CR]
- Study Progress Report Dated 02/23/06
- 03/27/06, DSMC Report



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

- 09/27/06: CIRB Acknowledgement of Paper Data for AALL03B1, AALL0232, and AALL0331
- 09/22/06: Memo of Paper Data for AALL03B1, AALL0232, and AALL0331

#### **COG-AALL03N1**

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

- 09/27/06: CIRB Acknowledgement of Training Module for AALL03N1
- 09/22/06: Memo of Training Module for AALL03N1

#### **COG-AALL05B1**

Continuing Review September 2006  
Documents Posted:

- CIRB Continuing Review Application Version 03/14/06
- 08/31/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 03/14/06)
- 07/21/06, Continuing Review Notice for September 2006
- Protocol Version 03/14/06
- Informed Consent for Protocol Version 03/14/06 [Per Sep. 06 CR]

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

- 09/27/06: CIRB Acknowledgement of Activation of AALL05B1
- 09/25/06: Memo of Activation of AALL05B1

#### **COG-ACNS0423**

Amendment #1 (dated 07/12/06)  
Documents Posted:

- 7/13/06: Change Memo
- CIRB Application Version 07/12/06
- 8/3/06: CIRB Approval (Protocol Version 7/12/06)
- Protocol Version 07/12/06
- Protocol Version, 7/12/06, Highlighted Changes
- Informed Consent for Protocol Version 07/12/06



Continuing Review September 2006  
Documents Posted:

- CIRB Continuing Review Application Version 07/12/06
- 06/27/06, Continuing Review Notice for September 2006
- 09/21/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 07/12/06)
- Protocol Version 07/12/06
- Informed Consent for Protocol Version 07/12/06 [Per Sep. 06 CR]
- Study Progress Report Dated 02/23/06
- 03/29/06, DSMC Report

**COG-ANBL00B1**

Continuing Review September 2006  
Documents Posted:

- CIRB Continuing Review Application Version 09/27/05
- 09/21/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 09/27/05)
- 06/27/06, Continuing Review Notice for September 2006
- Protocol Version 09/27/05
- Informed Consent for Protocol Version 09/27/05 [Per Sep. 06 CR]
- Study Progress Report Dated 02/23/06

**COG-ANBL0322**

Continuing Review September 2006  
Documents Posted:

- CIRB Continuing Review Application Version 05/22/06
- 09/21/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 05/22/06)
- 06/27/06, Continuing Review Notice for September 2006
- Protocol Version 05/22/06
- Informed Consent for Protocol Version 05/22/06 [Per Sep. 06 CR]
- 03/29/06, DSMC Report
- Study Progress Report Dated 02/23/06

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

Documents Posted:

- 09/27/06: CIRB Acknowledgement of Drug Return form for study ANBL0322, A Phase II study of hu14.18-IL2.....
- 09/22/06: Memo of Drug Return form for study ANBL0322, A Phase II study of hu14.18-IL2.....



### **COG-ANBL0421**

Continuing Review August 2006

Documents Posted:

- CIRB Continuing Review Application Version 04/01/06
- 08/10/06, CIRB Approval to Continuing Review August 2006 (Protocol Version 04/01/06)
- 05/31/06, Continuing Review Notice for August 2006
- Protocol Version 04/01/06
- Informed Consent for Protocol Version 04/01/06 [per August 2006 CR]
- 08/10/06: Primary Reviewer 1 Comments
- 08/10/06, Minutes: Continuing Review August 2006

### **COG-ANHL04B1**

Continuing Review September 2006

Documents Posted:

- CIRB Continuing Review Application Version 12/07/05
- 09/21/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 12/07/05)
- 06/27/06, Continuing Review Notice for September 2006
- Protocol Version 12/07/05
- Informed Consent for Protocol Version 12/07/05 [Per Sep. 06 CR]
- Study Progress Report Dated 02/23/06

### **COG-AOST0331**

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

Documents Posted:

- 09/27/06: CIRB Acknowledgement of Drug Return form for study AOST0331, A Randomized Trial of the European.....
- 09/22/06: Memo of Drug Return form for study AOST0331, A Randomized Trial of the European.....

### **COG-ARAR0332**

Amendment Review: Amendment #1 (Protocol Version 08/30/06)

Documents Posted:

- 08/30/06, Change Memo
- CIRB Application Version 08/30/06
- 09/18/06: CIRB Acknowledgement of Activation
- 09/18/06: Study Activation
- 09/06/06: CIRB Approval to Amendment #1 (Protocol Version 08/30/06)
- Protocol Version 08/30/06



- Protocol Version 08/30/06, Highlighted Changes
- Informed Consent for Protocol Version 08/30/06
- Informed Consent for Protocol Version 08/30/06: p53 Testing
- Informed Consent for Protocol Version 08/30/06: Blood Sample

Continuing Review May 2006  
Documents Posted:

- CIRB Continuing Review Application Version 12/13/05
- 05/05/06, CIRB Approval to Continuing Review May 2006 (Protocol Version 12/13/05): Local IRB
- 05/05/06, CIRB Approval to Continuing Review May 2006 (Protocol Version 12/13/05): Study Chair
- 03/29/06, Continuing Review Notice for May 2006
- Protocol Version 12/13/05
- Informed Consent for Protocol Version 12/13/05
- Informed Consent for Protocol Version 12/13/05: p53 Testing
- Informed Consent for Protocol Version 12/13/05: Blood Sample

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

- 09/27/06: CIRB Acknowledgement of No Objection Letter for ARAR0332, Treatment of Adrenocortical Tumors with.....
- 09/22/06: Memo of No Objection Letter for ARAR0332, Treatment of Adrenocortical Tumors with.....

#### **COG-AREN0321**

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

- 09/27/06: CIRB Acknowledgement of Correction of programming problem in RDE underway
- 09/22/06: Memo of Correction of programming problem in RDE underway

#### **ECOG-E4A03**

Amendment Review: Addendum #5 (Protocol Version 04/26/06)  
Documents Posted:

- 04/26/06: Change Memo
- CIRB Application Version 04/26/06
- Summary of CIRB Application Revisions



- 06/09/06: CIRB Approval to Addendum #5 (Protocol Version 04/26/06): Study Chair
- 06/09/06: CIRB Approval to Addendum #5 (Protocol Version 04/26/06): Local IRB
- Protocol Version 04/26/06
- Informed Consent for Protocol Version 04/26/06
- 06/02/06: Primary Reviewer 1 Comments
- 06/02/06, Minutes: Addendum #5 Review

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

Amendment Review: Update #2 (Protocol Version 08/23/06)

Documents Posted:

- 08/23/06, Change Memo
- CIRB Application Version 08/23/06
- Summary of CIRB Application Revisions Version 08/23/06
- 09/07/06: CIRB Approval to Update #2 (Protocol Version 08/23/06)
- Protocol Version 08/23/06
- Informed Consent for Protocol Version 08/23/06

#### **NCCTG-N0434(MA.27D)**

Continuing Review September 2006 (Other documents for this protocol were included in August 31, 2006 Study Activity Update)

Documents Posted:

- 08/04/06: Primary Reviewer 1 Comments
- 08/04/06, Minutes: Continuing Review August 2006

#### **RTOG-0525**

Amendment Review: Amendment #1 (Protocol Version 06/12/06)

Documents Posted:

- 06/12/06, Change Memo
- CIRB Application Version 06/12/06
- Summary of CIRB Application Revisions Version 06/12/06
- 09/01/06: CIRB Approval to Amendment #1 (Protocol Version 06/12/06)
- Protocol Version 06/12/06
- Appendix II-V
- Appendix VI-VIII
- Informed Consent for Protocol Version 06/12/06
- 09/01/06: Primary Reviewer 1 Comments
- 09/01/06: Minutes: Amendment #1 Review

#### **SWOG-S0307**

Continuing Review August 2006



#### Documents Posted:

- CIRB Continuing Review Application Version 06/12/06
- 05/11/06, Notification of Continuing Review July 2006
- 08/21/06, CIRB Approval to Continuing Review July 2006 (Protocol Version 05/23/05)
- Protocol Version 05/23/05
- Informed Consent for Protocol Version 05/23/05 [Per Aug. 06 CR]
- 05/19/06, DSMC Report
- 05/19/06, Toxicity Report

#### **SWOG-S0427**

Continuing Review September 2006

#### Documents Posted:

- CIRB Continuing Review Application Version 01/26/06
- 07/24/06, Continuing Review Notice for September 2006
- 09/07/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 01/26/06)
- Protocol Version 01/26/06
- Informed Consent for Protocol Version 01/26/06
- 09/01/06: Primary Reviewer 1 Comments
- 09/01/06, Minutes: Continuing Review September 2006
- 07/26/06, Report of Studies

### **Serious Adverse Events**

**Study: CALGB 80203**

**SAEs Posted: 06-02-09359 / DDL 225**

**Study: CALGB-SWOG 80405**

**SAEs Posted: 06-02-09359 / DDL 225**

**Study: CALGB-100104-ECOG-100104**

**SAEs Posted: 1750761, 1710444**

**Study: ECOG E1505**

**SAE Posted: 1322063**

**Study: ECOG E2100**

**SAE Posted: 1322063**

**Study: ECOG E4A03**

**SAEs Posted: 1750761, 1710444**



**Study: ECOG E4599**  
**SAE Posted: 1322063**

**Study: ECOG E5202**  
**SAE Posted: 1322063**

**Study: ECOG E5204**  
**SAE Posted: 1322063**

**Study: GOG 0219**  
**SAE Posted: 1384841**

**Study: NCCTG N0147**  
**SAEs Posted: 06-02-09359 (1) / DDL 225 (1), 06-02-09480 / DDL 228, 06-02-07899 (1) / DDL 210 (1), 06-02-08475 / DDL 221, 06-02-08706 / DDL 220**

**Study: NSABP B-38**  
**SAEs Posted: Safety Update #86, Safety Update #87, Safety Update #88, Safety Update #77 FU 1**

**Study: RTOG 0320**  
**SAEs Posted: 2006-07-0712, 2006-07-1249, 2006-07-0712 (1)**

**Study: RTOG 0522**  
**SAEs Posted: 04-02-04123 (2) / DDL 116 (2), 06-02-09124 (1) / DDL 224 (1), 06-02-09359 (1) / DDL 225 (1), 06-02-09480 / DDL 228, 06-02-08475 / DDL 221, 06-02-08706 / DDL 220, 05-02-06785 (3) / DDL 188 (3)**

**Study: RTOG 0525**  
**SAEs Posted: 2006-07-0712, 2006-07-0712 (1), 2006-07-1249**

**Study: SWOG S0205**  
**SAEs Posted: 06-02-09480 / DDL 228, 06-02-08706 / DDL 220, 06-02-09359 (1) / DDL 225 (1)**

**Study: SWOG S0232**  
**SAEs Posted: 1750761, 1710444**

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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).