



## NCI Central IRB Study Activity Update

May 30, 2008

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 – ALTE05N1**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version Date 02/12/08
- Protocol Version Date 02/12/08 - Highlighted Changes
- Protocol Version Date 10/04/07
- Protocol Version Date 10/04/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/12/08
- CIRB Application (Protocol Version Date 02/12/08)
- CIRB Application (Protocol Version Date 10/04/07)
- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Primary Reviewer 2 Comments
- 12/13/07: Primary Reviewer 3 Comments
- 02/29/08: CIRB Final Approval Letter (Protocol Version Date 02/12/08)
- 02/12/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/12/08)
- 01/15/08: CIRB Approval Pending Modification Letter (Protocol Version Date 10/04/07)
- 12/13/07: Minutes - Initial Review

## **Other Activity Posted:**

### **ACOSOG-Z1031**

Continuing Review (CR) Approval May 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/18/06)
- 05/16/08: CIRB Continuing Review Approval May 2008 (Protocol Version Date 12/18/06)
- Protocol Version Date 12/18/06
- Informed Consent Document for Protocol Version Date 12/18/06 [Per May 08 CR] Main
- Informed Consent Document for Protocol Version Date 12/18/06 [Per May 08 CR] Genome



- Informed Consent Document for Protocol Version Date 12/18/06 [Per May 08 CR] Spec Bank
- 08/17/07: DMC Summary
- 07/17/07: Study Summary

#### **CALGB-40101**

Continuing Review (CR) Approval May 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/08/07)
- 05/28/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/08/07)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 11/08/07
- Informed Consent Document for Protocol Version Date 11/08/07
- Study Summary

#### **COG-AALL03B1**

Continuing Review (CR) Approval May 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/24/08)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/24/08)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/24/08
- Informed Consent Document for Protocol Version Date 01/24/08 - Additional Bone Marrow
- Informed Consent Document for Protocol Version Date 01/24/08 - Study Entry & Shipment of Samples
- 02/04/08: Study Progress Report

#### **COG-AALL0331**

Continuing Review (CR) Approval May 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/25/06)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/25/06)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/25/06
- Informed Consent Document for Protocol Version Date 09/25/06: Induction Therapy
- Informed Consent Document for Protocol Version Date 09/25/06: Standard Risk - High



- Informed Consent Document for Protocol Version Date 09/25/06: Standard Risk - Average
- Informed Consent Document for Protocol Version Date 09/25/06: Standard Risk – Low
- 10/25/07: DSMC Report
- 10/01/07: Study Progress Report

#### **COG-ACNS0423**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/12/07)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 02/12/07
- Informed Consent Document for Protocol Version Date 02/12/07
- 10/25/07: DSMC Report
- 10/01/07: Study Progress Report

#### **COG-ADVL0525**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/12/07)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
- 03/06/08: CIRB Continuing Review Reminder Notice (Protocol Version Date 02/12/07)
- Protocol Version Date 02/12/07
- Informed Consent Document for Protocol Version Date 02/12/07
- 02/04/08: Study Progress Report

#### **COG-AEWS0621**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/06/07)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/06/07)
- 03/06/08: Continuing Review Reminder Notice
- Protocol Version Date 11/06/07
- Informed Consent Document for Protocol Version Date 11/06/07
- 04/11/08: Data Safety Monitoring Committee Report
- 02/04/08: Study Progress Report



### **COG-ARST0431**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application ( Protocol Version Date 06/26/07)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/07)
- 03/18/08:CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/26/07
- Informed Consent Document for Protocol Version Date 06/26/07
- 02/04/08: Study Progress Report

### **ECOG-E1302**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/17/07)
- 05/29/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/17/07)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 10/17/07
- Informed Consent Document for Protocol Version Date 10/17/07 [Per May 08 CR]
- November 2007: Study Summary
- 09/24/07: DMC Recommendations

### **ECOG-E5202**

Amendment Review Update #2 Approval May 2008

Documents Posted:

- 04/16/08: Change Memo (Protocol Version Date 04/16/08)
- CIRB Application (Protocol Version Date 04/16/08)
- Summary of CIRB Application Revisions
- 05/08/08: CIRB Update #2 Approval Letter (Protocol Version Date 04/16/08)
- Protocol Version Date 04/16/08
- Informed Consent Document for Protocol Version Date 04/16/08



#### **GOG-0198**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/13/07)
- 05/28/08: CIRB Continuing Review Approval Letter (Protocol Version Date 12/13/07)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 12/13/07
- Appendix I FIGO
- Appendix II Specimen Procedure
- Appendix III Lab Procedure
- Appendix IV CRADA
- Appendix V Logistical Guidelines for CTSU
- Appendix V Logistical Guidelines for CTSU (Highlighted)
- January 2008: Study Summary
- 01/26/08: DSMB Minutes

#### **GOG-0204**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/06/06)
- 05/07/08: CIRB Continuing Review Approval Letter May 2008 (Protocol Version Date 09/06/06)
- 03/05/08: CIRB Continuing Review Reminder Notice for May 2008
- Protocol Version Date 09/06/06
- Informed Consent Document for Protocol Version Date 09/06/06 [per May 08 CR]
- 01/26/08: DSMB Minutes
- Statistical Report

#### **NCCTG-N0147**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/08/07)
- 05/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/08/07)
- 03/05/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/08/07
- Informed Consent Document for Protocol Version Date 10/08/07 [per May 08 CR]
- April 2008: Status Report



- 04/08/08: DMC Report
- 09/25/07: DMC Except

#### **NCIC-CTG-MA.27**

Amendment Review Amendment #9 Approval April 2008

Documents Posted:

- Change Memo
- CIRB Application (Protocol Version Date 04/07/08)
- Summary of CIRB Application Revisions
- 05/15/08: CIRB Amendment #9 Approval Letter (Protocol Version Date 04/07/08)
- Protocol Version Date 04/07/08 [Companion]
- Informed Consent Document for Protocol Version Date 04/07/08 [Companion]
- 04/21/08: Primary Reviewer 1 Comments
- 04/21/08: Minutes - Amendment #9 Review
- Patient Information Letter

#### **NCIC-CTG-MA.27B**

**\*\*Study Closed to Accrual Effective as of 6:00 pm EST on Friday May 30, 2008\*\***

#### **RTOG-0421**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/14/07)
- 05/16/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/14/07)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 02/14/07
- 01/11/08: DMC Minutes
- January 2008: Study Progress Report

#### **SWOG-S0012**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/02/08)
- 05/28/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/02/08)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 02/02/07
- Study Summary - October 2006



### **SWOG-S0106**

Amendment Review Revision #6 Approval April 2008

Documents Posted:

- CIRB Application Version 03/28/08
- Summary of CIRB Application Revisions (Protocol Version Date 03/28/08)
- CIRB Application Version 11/23/07
- Summary of CIRB Application Revisions (Protocol Version Date 11/23/07)
- 05/06/08: CIRB Acknowledgement of Activation Revision #6 (Protocol Version Date 03/28/08)
- 04/14/08: CIRB Revision #6 Approval Letter (Protocol Version Date 03/28/08)
- 03/27/08: CIRB Approval Pending Modification (Protocol Version Date 11/23/07)
- Protocol Version Date 03/28/08
- Protocol Version Date 11/23/07
- Informed Consent Document for Protocol Version 03/28/08 [per Rev 6]
- 03/07/08: Minutes: Revision #6 Review

### **SWOG-S0777**

**\*\*Temporarily Closed to Accrual - Effective May 13, 2008\*\***

- 05/13/08: CIRB Acknowledgement of Receipt - Temporary Closure to New Accrual
- 05/13/08: Notification of Temporary Closure to New Accrual
- January 2008: Study Progress Report

### **SWOG-S9925**

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/19/07)
- 05/28/08: Continuing Review Approval Letter (Protocol Version Date 10/19/07)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 10/19/07
- Study Summary - May 2007

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).