



## NCI Central IRB Study Activity Update January 15, 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.

### **Adult CIRB Studies**

#### **GOG-0213**

Initial Review 2007 Approval

Documents Posted:

- Protocol Version 09/12/07
- Protocol Version 06/29/07
- Protocol Version 04/13/07
- Informed Consent for Protocol Version 09/12/07
- CIRB Application for Treatment (Protocol Version 09/12/07)
- CIRB Application for Treatment (Protocol Version 06/29/07)
- CIRB Application for Treatment (Protocol Version 04/13/07)
- 12/06/07: Group Letter: Protocol GOG 0213 Activation
- 10/03/07: CIRB Initial Review Approval October 2007 (Protocol Version 09/12/07)
- 09/12/07: Group Letter: Response to CIRB Approval Pending Modification
- 08/22/07: CIRB Approval Pending Modification Group Response (Protocol Version 06/29/07)
- 06/29/07: Group Letter: Response to Table of Initial Review (Protocol Version 06/29/07)
- 06/18/07: CIRB Table of Initial Review (Protocol Version 04/13/07)
- 08/03/07: CIRB Minutes (Protocol Version 06/29/07)
- 06/01/07: CIRB Minutes (Protocol Version 04/13/07)
- 04/24/07: CTEP Notice of Protocol Approved on Hold (Protocol Version 04/13/07)
- 04/13/07: Group Response to Consensus Review 04/02/07



## **Pediatric CIRB Studies**

### **COG – AALL0631**

Initial Review 2007 Approval  
Documents Posted:

- Protocol Version Date 09/11/07
- Protocol Version Date 09/11/07 - Highlighted
- Protocol Version Date 06/07/07
- Protocol Version Date 06/07/07 – Highlighted
- CIRB Application (Protocol Version Date 09/11/07)
- CIRB Application (Protocol Version Date 06/07/07)
- 09/27/07: Primary Reviewer 1 Comments
- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Primary Reviewer 2 Comments
- 07/12/07: Primary Reviewer 3 Comments
- 07/12/07: Pharmacist Reviewer Comments
- 10/01/07: CIRB Final Approval (Protocol Version Date 09/11/07)
- 09/11/07: Group Response Letter
- 08/28/07: CIRB Approval Pending Modification (Protocol Version Date 06/07/07)
- 06/07/07: Change Letter
- 09/27/07: Minutes - Group Response to Initial Review
- 07/12/07: Minutes - Initial Review

### **COG – ASCT0631**

Initial Review 2006 Approval  
Documents Posted:

- Protocol Version Date 12/12/06
- Protocol Version Date 12/12/06 - Highlighted Version
- Protocol Version Date 09/11/06
- Protocol Version Date 09/11/06 - Highlighted Version
- Informed Consent Form for Protocol Version Date 10/29/07 - Assent Consent
- Informed Consent Form for Protocol Version Date 10/29/07 - Donor Consent
- Informed Consent Form for Protocol Version Date 10/29/07 - Recipient Consent
- CIRB Application (Protocol Version Date 12/12/06)



- CIRB Application (Protocol Version Date 09/11/06)
- 12/27/06: CIRB Final Approval (Protocol Version Date 12/12/06)
- 12/12/06: Group Response Letter
- 11/08/06: CIRB Approval Pending Modification to Initial Review (Protocol Version Date 09/11/06)
- 10/05/06: Group Cover Letter
- 09/11/06: Group Response Letter

### **Other Activities Posted:**

#### **CALGB-SWOG-C80405**

Continuing Review (CR): December 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/13/07)
- 01/08/08: CIRB Continuing Review Approval December 2007 (Protocol Version 06/13/07)
- Protocol Version 06/13/07
- Informed Consent Form for Protocol Version 06/13/07 [per Dec 07 CR]
- Study Summary Dated June 2007

#### **COG – AALL03N1**

Continuing Review (CR): October 2007

Documents Posted:

- 10/11/07: Primary Reviewer 1 Comments
- 10/11/07: Minutes - Continuing Review

Continuing Review (CR): January 2007

Documents Posted:

- 12/14/06: Minutes - Continuing Review

Continuing Review (CR): February 2006

Documents Posted:

- 02/09/06: Primary Reviewer 1 Comments
- 02/09/06: Minutes - Continuing Review



Amendment Review (AR): AALL03N1 Information Booklet Review  
Documents Posted:

- 03/28/07: CIRB Approval March 2007
- 02/05/07: Information Booklet Memo
- Information Booklet
- 03/08/07: Minutes - Recruitment Material

**COG – AALL0631**

Amendment Review (AR): Amendment #AA1 (Protocol Version Date 11/02/07)  
Documents Posted:

- CIRB Initial Review Application (Protocol Version 11/02/07)
- 11/21/07: CIRB Amendment Review Approval November 2007 (Protocol Version 11/02/07)
- 11/02/07: Group Activation Letter
- Protocol Version 11/02/07
- Informed Consent Part 1 non-Phase 1 for Protocol Version Date 11/02/07 [per Am #AA1]
- Informed Consent Part 1 Phase 1 Inst for Protocol Version Date 11/02/07 [per Am #AA1]
- Informed Consent Part 2 for Protocol Version Date 11/02/07 [per Am #AA1]

**COG – AAML06P1**

Continuing Review (CR): December 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/26/07)
- 01/02/08: CIRB Approval to Continuing Review December 2007 (Protocol Version Date 02/26/07)
- Protocol Version Date 02/26/07
- Informed Consent Form for Protocol Version Date 02/26/07

**COG – ACCL05C1**

Continuing Review (CR): December 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/30/07)
- 01/02/08: CIRB Approval to Continuing Review December 2007 (Protocol Version Date 01/30/07)
- Protocol Version Date 01/30/07
- Informed Consent Form for Protocol Version 01/30/07
- Study Progress Report Dated June 2007



**COG – ACCRN07**

Initial Review: 2007  
Documents Posted:

- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Primary Reviewer 2 Comments
- 03/08/07: Primary Reviewer 3 Comments
- 03/08/07: Minutes - Initial Review

**COG – ACNS0222**

Continuing Review (CR): December 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/08/07)
- 01/02/08: CIRB Approval to Continuing Review December 2007 (Protocol Version Date 05/08/07)
- Protocol Version Date 05/08/07
- Informed Consent Form for Protocol Version Date 05/08/07
- 10/05/07: FDA Warning Letter

**COG – ADVL0525**

Initial Review: Correction  
Documents Posted:

- 02/12/07: Group Response Letter

**COG – ANBL00P3**

Continuing Review (CR): October 2007  
Documents Posted:

- 10/11/07: Primary Reviewer 1 Comments
- 10/11/07: Minutes - Continuing Review

**COG – ANBL0532**

Initial Review: October 2007  
Documents Posted:

- 10/11/07: Primary Reviewer 1 Comments
- 10/11/07: Minutes - Initial Review

**COG – ARAR0332**

Continuing Review (CR): December 2007



Documents Posted:

- CIRB Continuing Review Application (Protocol version 08/30/06)
- 01/10/08: CIRB Continuing Review Approval December 2007 (Protocol Version 08/30/06)
- 01/09/08: COG Response Letter
- 01/08/08: CIRB Approval Pending Modifications
- Protocol Version 08/30/06
- Informed Consent Form for Protocol Version 08/30/06 [per CR Dec 07]
- Informed Consent Form for Protocol Version 08/30/06: Blood Sample [per CR Dec 07]
- Informed Consent Form for Protocol Version 08/30/06: p53 Testing [per CR Dec 07]
- Study Progress Report-Fall 2007

**COG – AREN0532**

Continuing Review: November 2007

Documents Posted:

- 11/08/07: Primary Reviewer 1 Comments
- 11/08/07: Minutes - Continuing Review

**COG – AREN0533**

Continuing Review (CR): December 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 11/14/06)
- 01/10/08: CIRB Continuing Review Approval December 2007 (Protocol Version 11/14/06)
- 01/09/08: COG Response Letter
- 01/08/08: CIRB Approval Pending Modification
- Protocol Version 11/14/06
- Informed Consent for Protocol Version 11/14/06 [per CR Dec 07]
- Study Progress Report-Fall 2007

**COG – ARST0332**

Continuing Review (CR): October 2007

Documents Posted:

- 10/11/07: Primary Reviewer 1 Comments
- 10/11/07: Minutes - Continuing Review

**COG – ASCT0631**



Amendment Review (AR): October 2007  
Documents Posted:

- CIRB Application (Protocol Version Date 10/29/07)
- 12/07/07: CIRB Amendment Approval (Protocol Version Date 10/29/07)
- 10/29/07: Change Letter
- Protocol Version Date 10/29/07
- Protocol Version Date 10/29/07 - Highlighted Version
- 11/08/07: Primary Reviewer 1 Comments
- 11/08/07: Minutes - Continuing Review

Amendment Review (AR): August 2007  
Documents Posted:

- CIRB Application (Protocol Version Date 09/26/07)
- CIRB Application (Protocol Version Date 08/07/07)
- 10/10/07: CIRB Approval to Activation Amendment October 2007 (Protocol Version Date 09/26/07)
- 09/26/07: Group Response Letter
- 09/25/07: CIRB Approval Pending Modification (Protocol Version Date 08/07/07)
- 08/07/07: Change Memo
- Protocol Version Date 09/26/07
- Protocol Version Date 08/07/07
- Protocol Version Date 08/07/07 - Highlighted Version

Continuing Review (CR): July 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/12/06)
- 07/31/07: CIRB Approval to Continuing Review July 2007 (Protocol Version Date 12/12/06)



### **ECOG-E2902**

Continuing Review (CR) December 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/06/07)
- 12/26/07: CIRB Continuing Review Approval December 2007 (Protocol Version 09/06/07)
- Protocol Version 09/06/07
- Informed Consent for Protocol Version 09/06/07 [per Dec 07 CR]
- November 2007: Toxicity Summary
- 10/05/07: DMC Minutes
- Date 12/12/06)

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

Patient Education Material  
Documents Posted:

- 09/19/07: CIRB Approval of the Recruitment Materials
- 05/25/07: CIRB Approval Pending Modification-Patient Recruitment Material
- 09/25/06: CIRB Approval of Patient Materials
- 09/19/06: CIRB Acknowledgement of Receipt-Patient Materials
- Randomization Fact Sheet
- 05/04/07: Meeting Minutes

### **GOG-0198**

Amendment Review (AR) Closure to Accrual July 2007 Approval  
Documents Posted:

- 07/30/07: Notification of Closure to Accrual

### **NCIC CTG-PR.11**

Continuing Review (CR) December 2007 Approval  
Documents Posted:

- CIRB Continuing Review Application
- 01/07/08: CIRB Continuing Review Approval December 2007 (Protocol Version 05/18/07)
- Protocol Version 05/18/07
- Informed Consent Form for Protocol Version Date 05/18/07 [per Dec 07 CR]



#### **RTOG-0415**

Amendment Review (AR) Amendment #2 December 2007 Approval  
Documents Posted:

- 12/03/07: Summary of Changes
- 09/20/07: Summary of Changes
- 04/18/06: Summary of Changes
- CIRB Review Application (Protocol Version 12/03/07)
- Summary of CIRB Application Revisions (Protocol Version 12/03/07)
- CIRB Review Application (Protocol Version 09/20/07)
- Summary of CIRB Application Revisions (Protocol Version 09/20/07)
- 12/26/07: CIRB Amendment #2 Approval December 2007 (Protocol Version 12/03/07)
- 12/03/07: CIRB Approval Pending Modifications November 2007 (Protocol Version 09/20/07)
- Protocol Version Date 12/03/07
- Protocol Version Date 12/03/07 [tracked]
- Protocol Version Date 09/20/07
- Protocol Version Date 09/20/07 [tracked]
- Informed Consent Form for Protocol Version Date 12/03/07 [per Am 2 Dec 07]

#### **RTOG-0525**

Amendment Review (AR) Amendment #3 November 2007 Approval  
Documents Posted:

- 10/30/07: Summary of Changes
- 08/02/07: Summary of Changes
- 07/12/07: Summary of Changes
- Appendix VII (Fillable Form for Web)
- Appendix X NCCTG (Revised for Am 3) Untracked
- Appendix X NCCTG (Revised for Am 3) Tracked
- CIRB Review Application (Protocol Version 10/30/07)
- Summary of CIRB Application Revisions (Protocol Version 10/30/07)
- Summary of CIRB Application Revisions (Protocol Version 08/02/07)
- CIRB Review Application (Protocol Version 08/02/07)
- 12/03/07: CIRB Group Response Approval November 2007 (Protocol Version 10/30/07)
- 10/30/07: Group Response Letter
- 09/24/07: CIRB Approval Pending Modifications
- 08/02/07: Group Cover Letter
- Protocol Version 10/30/07



- Protocol Version 10/30/07-Tracked
- Protocol Version 08/02/07
- Protocol Version 08/02/07-Tracked
- Informed Consent for Protocol Version 10/30/07 [per Am#3 Nov 07]

#### **SWOG-9007**

Amendment Review (AR) Revision #33 September 2007 Approval  
Documents Posted:

- CIRB Application for Ancillary Protocol (Protocol Version 08/27/07)
- Summary of CIRB Application Revisions
- 09/19/07: CIRB Approval Revision #33 September 2007 (Protocol Version 08/27/07)
- Protocol Version Date 08/27/07
- Informed Consent Form for Protocol Version Date 08/27/07 [per Rev#33]

#### **SWOG-9007**

Amendment Review (AR) Revision #34 December 2007 Approval  
Documents Posted:

- CIRB Review Application (Protocol Version 11/29/07)
- Summary of CIRB Application Revisions
- 12/26/07: CIRB Review Approval Revision #34 December 2007 (Protocol Version 11/29/07)
- Protocol Version 11/29/07
- Informed Consent Form for Protocol Version Date 11/29/07 [per Rev#34]

#### **SWOG-S9910**

Amendment Review (AR) Revision #15 December 2007 Approval  
Documents Posted:

- CIRB Review Application (Protocol Version 11/29/07)
  - Summary of CIRB Application Revisions
  - 12/26/07: CIRB Review Approval Revision #15 December 2007 (Protocol Version 11/29/07)
  - Protocol Version 11/29/07
  - Informed Consent Form for Protocol Version Date 11/29/07 [per Rev #15]
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## Corrections to Previous Study Activity Updates

### ECOG-PACCT-1

Amendment Review Amendment #5 Approval

Documents Posted:

Informed Consent for Protocol Version 11/14/07 [per Am 5 Dec 07] REVISED

Correction:

Informed Consent replaced because of pagination problem.

### NSABP-B42

Amendment Review Continuing Review Approval

Documents Posted:

12/26/07: ERRATUM: CIRB Approval Expiration Date

Correction:

The NSABP B-42 Continuing Review Approval Letter posted on the CIRB website and dated November 30, 2007 contains two errors:

- 1) The subject line should read **“CIRB Approval of Continuing Review of NSABP B-42”** instead of **“CIRB Approval pending modification of Continuing Review of NSABP B-42”**
- 2) The protocol version date listed in the third section of the letter should read **“7/12/06”** instead of **“7/12/2007”**.

### SWOG-S0421

Amendment Review Continuing Review Approval

Documents Posted:

Informed Consent for Protocol Version 02/01/07 [per Nov 07 CR] REVISED

Correction:

Informed Consent revised because of pagination problem.

### SWOG-S0600

Initial Review 2006

Documents Posted:

08/04/06: Minutes: Initial Review

Correction:

The minutes were never posted for the above reference study. It was conditionally approved pending modifications on August 4, 2006.



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).