



## NCI Central IRB Study Activity Update

October 15, 2007

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 – ANBL0531**

Initial Review 2006 Approval  
Documents Posted:

- Protocol Version Date 05/01/07
- Protocol Version Date 05/01/07 Highlighted
- Protocol Version Date 04/09/07
- Protocol Version Date 04/09/07 Highlighted
- Protocol Version Date 02/06/07
- Protocol Version Date 02/06/07 Highlighted
- Protocol Version Date 10/10/06
- Protocol Version Date 10/10/06 Highlighted
- CIRB Application (Protocol Version Date 05/01/07)
- CIRB Application (Protocol Version Date 04/09/07)
- CIRB Application (Protocol Version Date 02/06/07)
- CIRB Application (Protocol Version Date 10/10/06)
- 11/30/06, Primary Reviewer 1 Comments
- 11/30/06, Primary Reviewer 2 Comments
- 11/30/06, Primary Reviewer 3 Comments
- 05/31/07, CIRB Final Approval (Protocol Version Date 05/01/07)
- 05/01/07, CIRB Approval Pending Modification of the Group Response (Protocol Version Date 04/09/07)
- 04/30/07, CIRB Approval Pending Modification of the Group Response (Protocol Version Date 04/09/07)
- 04/09/07, CIRB Approval Pending Modification of the Group Response (Protocol Version Date 02/06/07)
- 03/20/07, CIRB Approval Pending Modification of the Group Response (Protocol Version Date 02/06/07)
- 02/06/07, Table (Protocol Version Date 10/10/06)
- 12/27/06, Table (Protocol Version Date 10/10/06)
- 11/30/06, Initial Review Meeting Minutes

## **Other Activity Posted:**

### **CALGB-100104**

Continuing Review (CR): September 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/09/07)
- 10/08/07: CIRB Continuing Review Approval September 2007 (Protocol Version 04/09/07)
- Protocol Version 04/09/07 (includes update #5)



- Informed Consent Form for Protocol Version 04/09/07 [per Sep 07 CR]
- Study Summary Dated June 2007

#### **CALGB-40302**

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/28/07)
- 10/12/07: CIRB Continuing Review Approval October 2007 (Protocol Version 03/28/07)
- Protocol Version 03/28/07
- Informed Consent for Protocol Version 03/28/07 [per Oct. 07 CR]
- Study Summary Dated June 2007

#### **CALGB-50303**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/17/07)
- 09/27/07: CIRB Continuing Review Approval September 2007 (Protocol Version 04/17/07)
- Protocol Version 04/17/07
- Informed Consent for Protocol Version 04/17/07 [per Sep 07 CR]
- Toxicity Summary Dated June 2007

#### **CALGB-80101**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/22/07)
- 10/01/07: CIRB Continuing Review Approval September 2007 (Protocol Version 01/22/07)
- Protocol Version 01/22/07 (includes Update #5)
- Informed Consent for Protocol Version 01/22/07 [per Sep 07 CR]
- Study Summary Dated June 2007
- Toxicity Summary Dated October 2007

#### **CALGB-90104**

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/26/07)
- 10/08/07: CIRB Continuing Review Approval August 2007 (Protocol Version 03/26/07)
- Protocol Version 03/26/07 (includes Update #4)



- Study Summary Dated June 06

#### **CALGB-90206**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/26/07)
- 09/27/07: Continuing Review Approval September 2007 (Protocol Version 03/26/07)
- Protocol Version 03/26/07
- Study Summary Dated October 2006

#### **COG – AALL0433**

Continuing Review (CR) September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/23/07)
- 10/08/07: CIRB Approval for Continuing Review September 2007 (Protocol Version Date 02/23/07)
- Protocol Version Date 02/23/07
- Informed Consent Form for Protocol Version 02/23/07 [per Sep 2007 CR]
- 10/01/07: Study Progress Report

#### **COG – AALL05B1**

Amendment Review: Amendment #1

Documents Posted:

- CIRB Application (Protocol Version Date 09/06/07)
- 10/01/07, CIRB Approval to Amendment #2 (Protocol Version Date 09/06/07)
- 09/06/07, Change Memo
- Protocol Version Date 09/06/07
- Protocol Version Date 09/06/07 Highlighted
- Informed Consent Form (Protocol Version Date 09/06/07)

#### **COG – AALL06N1**

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/04/06)
- 09/28/07: CIRB Approval for Continuing Review August 2007 (Protocol Version Date 12/04/06)
- 09/18/07: Group Response to Approval Pending Modifications
- 09/17/07: CIRB Approval Pending Modifications for Continuing Review August 2007 (Protocol Version Date 12/04/06)



- Protocol Version Date 12/04/06
- Informed Consent for Protocol Version Date 12/04/06 [Per August 07 CR]

#### **COG – ACCL04C2**

Amendment Review: Amendment #1  
Documents Posted:

- CIRB Application (Protocol Version Date 09/11/07)
- 09/17/07: CIRB Approval for Amendment #1 (Protocol Version Date 09/11/07)
- 09/11/07: Change Memo
- Protocol Version Date 09/11/07
- Protocol Version Date 09/11/07 Highlighted
- Informed Consent Form (Protocol Version Date 09/11/07)

#### **COG – ADVL0524**

Continuing Review (CR) September 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/13/07)
- 10/08/07: CIRB Approval for Continuing Review September 2007 (Protocol Version Date 02/13/07)
- Protocol Version 02/13/07
- Informed Consent Form for Protocol Version 02/13/07 [per Sep 2007 CR]
- 04/20/07: DSMC Report
- 10/01/07: Study Progress Report

#### **COG – AHOD0431**

Continuing Review (CR): August 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/19/05)
- 09/28/07: CIRB Approval for Continuing Review August 2007 (Protocol Version Date 10/19/05)
- 09/18/07: Group Response to Approval Pending Modifications
- 09/17/07: CIRB Approval Pending Modifications for Continuing Review August 2007 (Protocol Version Date 10/19/05)
- Protocol Version 10/19/05
- Informed Consent Form for Protocol Version 05/11/07: Initial Treatment [Per August 07 CR]
- Informed Consent Form for Protocol Version 05/11/07: Relapse Treatment [Per August 07 CR]
- Informed Consent Form for Protocol Version 10/19/05: Initial Treatment [Per August 07 CR]



- Informed Consent Form for Protocol Version 10/19/05: Relapse Treatment [Per August 07 CR]
- 04/20/07: DSMC Report
- 03/30/07: Study Progress Report

#### **COG – ANBL0531**

Amendment Review: Activation Amendment  
Documents Posted:

- CIRB Application (Protocol Version Date 09/12/07)
- 09/20/07, Approval to Activation Amendment September 2007 (Protocol Version Date 09/12/07)
- 09/12/07, Change Memo
- Protocol Version Date 09/12/07
- Protocol Version Date 09/12/07 Highlighted
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment Group 2
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment Group 3
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment Group 4
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment for Residual or Recurrent, Localized Neuroblastoma

#### **COG – AOST0331**

Amendment Review: Amendment #2  
Documents Posted:

- CIRB Application (Protocol Version Date 09/21/07)
- CIRB Application (Protocol Version Date 06/28/07)
- 09/27/07, CIRB Full Board Approval to Amendment #2
- 09/21/07, Change Letter
- 09/10/07, CIRB Approval to Pending Modification Amendment #2
- Protocol Version Date 09/21/07
- Protocol Version Date 09/21/07 Highlighted
- Protocol Version Date 06/28/07
- Protocol Version Date 06/28/07 Highlighted
- Informed Consent for Protocol Version Date 09/21/07: Part 1: Induction Therapy
- Informed Consent for Protocol Version Date 09/21/07: Part 2: Good Response
- Informed Consent for Protocol Version Date 09/21/07: Part 2: Poor Response



### **COG – AREN0321**

Continuing Review (CR): August 2007

Documents Posted:

- Continuing Review Application (Protocol Version Date 11/20/06)
- 10/01/07: Erratum: CIRB Risk Determination Correction Letter
- 09/24/07: CIRB Approval to Continuing Review August 2007 (Protocol Version Date 11/20/06)
- 09/19/07: Response Letter
- 09/17/07: CIRB Approval Pending Modifications to Continuing Review August 2007 (Protocol Version Date 11/20/06)
- Informed Consent Form Protocol Version 11/20/06: Regimen DD-4A
- Informed Consent Form Protocol Version 11/20/06: Observation
- Informed Consent Form Protocol Version 11/20/06: Regimen I
- Informed Consent Form Protocol Version 11/20/06: Regimen UH1
- Informed Consent Form Protocol Version 11/20/06: Window Therapy
- 04/20/07: DSMC Report
- 03/30/07: Study Progress Report

### **COG – ARET0331**

Amendment Review: Amendment #1

Documents Posted:

- CIRB Application (Protocol Version Date 09/14/07)
- CIRB Application (Protocol Version Date 04/17/06)
- 09/17/07, CIRB Approval to Amendment #2 (Protocol Version Date 09/14/07)
- 09/14/07: Group Response to Approval Pending Modifications
- Protocol Version Date 09/14/07
- Protocol Version Date 09/14/07 Highlighted
- Protocol Version Date 04/17/06
- Informed Consent Form Protocol Version Date 09/14/07 [Per Sept. 07 CR]

### **COG – ARET0332**

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/05/06)
- 09/28/07: CIRB Approval for Continuing Review August 2007 (Protocol Version Date 09/05/06)
- 09/19/07: Group Response to Approval Pending Modifications
- 09/17/07: CIRB Approval Pending Modifications for Continuing Review August 2007 (Protocol Version Date 09/05/06)
- Protocol Version 09/05/06



- Informed Consent for Protocol Version 09/05/06: Chemotherapy Arm [Per August 07 CR]
- Informed Consent for Protocol Version 09/05/06: Observation Arm [Per August 07 CR]
- 04/17/07: DSMC Report
- 03/30/07: Study Progress Report

#### **ECOG-E1301**

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/21/03)
- 09/19/07: CIRB Continuing Review Approval August 2007 (Protocol Version 08/21/03)
- Protocol Version 08/21/03
- Report of Studies Dated June 2005
- 11/02/04: DMC Report

#### **ECOG-E1899**

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/16/04)
- 10/11/07: CIRB Continuing Review Approval October 2007 (Protocol Version 06/16/04)
- Protocol Version 06/14/04
- 11/02/04: DMC Report

#### **ECOG-E3805**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/02/07)
- 10/09/07: CIRB Continuing Review Approval September 2007 (Protocol Version 01/02/07)
- Protocol Version 01/02/07
- Informed Consent Form for Protocol Version 01/02/07 [Per Sep 07 CR]
- Report of Studies Dated June 2007
- 03/26/07, 05/20/07: DMC Report

#### **ECOG – E4599**

Amendment Review: Addendum #11

Documents Posted:

- 01/19/07: Change Memo



- 03/14/07, Approval to Addendum #11
- Protocol Version Date 01/19/07

#### **ECOG-E6201**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/07/07)
- 10/05/07: CIRB Continuing Review Approval September 2007 (Protocol Version 03/07/07)
- Protocol Version 03/07/07 (includes Update #1)
- Report of Studies Dated Jun 2006
- 04/27/04: DMC Report

#### **NSABP-B-38**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/17/07)
- 10/04/07: CIRB Continuing Review Approval September 2007 (Protocol Version 04/17/07)
- 08/24/07: Cover Letter
- Protocol Version 04/17/07
- 04/13/07: DMC Report
- 10/20/06: DMC Report
- Report of Studies Dated 2006

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

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/21/06)
- 09/27/07: CIRB Continuing Review Approval September 2007 [per Sep 07 CR]
- Protocol Version 04/21/06
- 04/13/07: DMC Report
- 10/20/06: DMC Report
- Report of Studies Dated September 2007
- 08/07/07: Cover Letter



### **NSABP-C-09**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/14/07)
- 10/05/07: CIRB Continuing Review Approval September 2007 (Protocol Version 06/14/07)
- 08/27/07: Cover Letter
- 08/09/07: NSABP-CTEP IND Info Memo
- Protocol Version 06/14/07
- Informed Consent Form for Protocol Version Date 06/14/07
- Report of Studies Dated Sep 2007
- DMC Report 04/13/07
- DMC Report 10/20/06

### **NSABP-R-04**

Amendment Review: Amendment #3

Documents Posted:

- Summary of CIRB Application Revisions (Protocol Version Date 06/12/07)
- Summary of CIRB Application Revisions (Protocol Version Date 03/30/07)
- CIRB Application (Protocol Version Date 03/30/07)
- CIRB Application Revision Summary (Protocol Version Date 03/30/07)
- 06/26/07: Approval Letter
- 05/23/07: CIRB Approval Pending Modification-Full Board
- 06/21/07: Response from the Group
- 04/03/07: Amendment Request Letter
- Protocol Version Date 06/12/07
- Protocol Version Date 03/30/07
- Tissue Sample Informed Consent Form for Protocol Version Date 06/12/07
- Informed Consent Form for Protocol Version 06/12/07
- 05/04/07: Minutes: Amendment Review

### **RTOG-0320**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/08/07)
- 10/08/07: CIRB Continuing Review Approval September 2007 (Protocol Version 05/08/07)
- Protocol Version 05/08/07
- Informed Consent Form for Protocol Version 05/08/07 [per Sep 07 CR]
- Report of Studies Dated June 2007
- 06/15/07: DMC Report



### **RTOG-0412-SWOG-S0332**

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/14/07)
- 10/11/07: CIRB Continuing Review Approval October 2007 (Protocol Version 02/14/07)
- Protocol Version 02/14/07
- 06/15/07: DMC Report
- Summary of Changes (Amendment 4)
- Report of Studies Dated June 2007

### **RTOG-0415**

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/24/07)
- 10/11/07: Continuing Review Approval October 2007 (Protocol Version 01/24/07)
- Protocol Version 01/24/07 (Amend 1)
- Informed Consent for Protocol Version 01/24/07 [per Oct 07 CR]
- Report of Studies June 2007
- 06/15/07: DMC Report

### **SWOG-S0023**

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/25/07)
- 09/19/07: CIRB Continuing Review Approval September 2007 (Protocol Version 07/25/07)
- Protocol Version (07/25/07) includes revision #16
- Addendum A: Paper Presented at ASCO 2007
- Report of Studies Addendum B Dated May 3-6 2007

Amendment Review: Revision #16

Documents Posted:

- 10/08/07: Approval Letter
- Protocol Version Date 07/25/07



## **Serious Adverse Events**

**Study: COG-ADVL0524**  
**SAE Posted: 1389196, 1402677, 1683941, 1890851**

**Study: ECOG E1505**  
**SAE Posted: 240958**

**Study: NSABP C-08**  
**SAE Posted: 240958**

**Study: SWOG S0600**  
**SAE Posted: 240958**

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).