



## NCI Central IRB Study Activity Update February 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.

---

### General CIRB Documentation

If other individuals at your institution need to receive this email or other CIRB Correspondence please have them email <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>). **\*\***

---

### 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-ARST0332**

Initial Review 2006

Documents Posted:

- Protocol Version Date 02/21/06
- Protocol Version Date 10/24/05
- Informed Consent for Protocol Version Date 02/21/06
- Informed Consent for Protocol Version Date 10/24/05
- CIRB Application Version (10/24/05)
- 03/20/06: Primary Reviewer 1 Comments
- 03/20/06: Primary Reviewer 2 Comments
- 03/20/06: Primary Reviewer 3 Comments
- 12/08/05: Pharmacy Review
- 12/08/05: Primary Reviewer 1 Comments
- 12/08/05: Primary Reviewer 2 Comments
- 12/08/05: Primary Reviewer 3 Comments
- 04/07/06: CIRB Approval (Protocol Version Date 02/21/06)
- 04/07/06: Approval Letter (Protocol Version Date 02/21/06)
- 01/09/06: CIRB Tabled Letter (Protocol Version Date 10/24/05)
- 01/09/06: COG Response to Protocol Disparities between ARST0431 and ARST0332
- 03/20/06: Group Response Meeting Minutes

#### **COG-AALL06N1**

Initial Review 2006 [Other documents for this protocol have been included in January 31, 2007 Study Activity Update]

Documents Posted:

- 10/26/06: Member 1 Comments
- 10/26/06: Member 2 Comments
- 10/26/06: Primary Reviewer 1 Comments
- 10/26/06: Primary Reviewer 2 Comments
- 10/26/06: Primary Reviewer 3 Comments



## **Other Activity Posted:**

### **CALGB-70301**

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/07/06)
- 02/01/07: CIRB Continuing Review Approval January 2007 (Protocol Version 07/07/06)
- Protocol Version 07/07/06
- Informed Consent for Protocol Version 07/07/06 [Per Jan. 07 CR]

### **COG-AALL03B1**

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in September 29, 2006 Study Activity Update]

Documents Posted:

- 09/14/06: Primary Reviewer 1 Comments

### **COG-AALL03N1**

Continuing Review (CR) January 2007 [Other documents for this protocol have been included in January 31, 2007 Study Activity Update]

Documents Posted:

- 12/14/06: Member 1 Comments
- 12/14/06: Primary Reviewer 1 Comments

### **COG-AAML0531**

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/30/06: Primary Reviewer 1 Comments

### **COG-ACCL04C2**

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

Documents Posted:

- 10/12/06: Primary Reviewer 1 Comments



#### **COG-ACNS0221**

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

Documents Posted:

- 10/12/06: Primary Reviewer 1 Comments

#### **COG-ACNS0224**

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in November 15, 2006 Study Activity Update]

Documents Posted:

- 09/28/06: Member 1 Comments
- 09/28/06: Primary Reviewer 1 Comments

#### **COG-ACNS0423**

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in September 29, 2006 Study Activity Update]

Documents Posted:

- 09/14/06: Primary Reviewer 1 Comments

#### **COG-ADVL0524**

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/30/06: Primary Reviewer 1 Comments

#### **COG-AHOD03P1**

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

Documents Posted:

- 10/12/06: Primary Reviewer 1 Comments

#### **COG-AHOD0431**

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 15, 2006 Study Activity Update]

Documents Posted:

- 10/26/06: Primary Reviewer 1 Comments



#### **COG-ANBL00B1**

Amendment Review: Amendment #6 (Protocol Version 08/18/06) [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 09/28/06: Primary Reviewer 1 Comments

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in September 29, 2006 Study Activity Update]

Documents Posted:

- 09/14/06: Primary Reviewer 1 Comments

#### **COG-ANBL00P3**

Continuing Review (CR) March 2006 [Other documents for this protocol have been included in March 31, 2006 Study Activity Update]

Documents Posted:

- 12/14/06: Member 1 Comments
- 12/14/06: Primary Reviewer 1 Comments

#### **COG-ANHL04B1**

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in September 29, 2006 Study Activity Update]

Documents Posted:

- 09/14/06: Primary Reviewer 1 Comments

#### **COG-ARAR0331**

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

Documents Posted:

- 10/12/06: Primary Reviewer 1 Comments

#### **COG-AREN0321**

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

Documents Posted:

- 10/26/06: Primary Reviewer 1 Comments



#### **COG-AREN0532**

Amendment Review: Amendment #1 (Protocol Version 07/28/06) [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 09/14/06: Member 1 Comments
- 09/14/06: Primary Reviewer 1 Comments

#### **COG-ARET0331**

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 30, 2006 Study Activity Update]

Documents Posted:

- 10/12/06: Member 1 Comments
- 10/12/06: Primary Reviewer 1 Comments

#### **COG-ARET0332**

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

Documents Posted:

- 10/26/06: Primary Reviewer 1 Comments
- 09/28/06: Member 1 Comments
- 09/28/06: Primary Reviewer 1 Comments

#### **COG-ARST03P1**

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

Documents Posted:

- 09/28/06: Primary Reviewer 1 Comments

#### **COG-ARST0332**

Amendment Review: Amendment #1 (Protocol Version 08/22/06)

Documents Posted:

- 08/24/06: Change Memo
- 10/21/05: CTEP Change Memo
- CIRB Application Version (08/22/06)
- 10/24/06: CIRB Amendment 1 Approval Letter (Protocol Version Date 08/22/06)
- Protocol Version Date 08/22/06, Highlighted Changes
- Protocol Version Date 08/22/06



- Informed Consent for Protocol Version Date 08/22/06

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/22/06)
- 12/26/06: CIRB Continuing Review Approval Letter
- Protocol Version Date 08/22/06, Highlighted Changes
- Protocol Version Date 08/22/06
- Informed Consent for Protocol Version Date 08/22/06 [per Dec 06 CR]

#### **COG-ARST0531**

Amendment Review: Amendment #2 (Protocol Version 10/16/06) [Other documents for this protocol have been included in December 29, 2006 Study Activity Update]

Documents Posted:

- 11/30/06: Member 1 Comments
- 11/30/06: Primary Reviewer 1 Comments

#### **COG-D9902**

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

Documents Posted:

- 09/28/06: Primary Reviewer 1 Comments

#### **ECOG-E4201**

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/26/05)
- 02/01/07: CIRB Continuing Review Approval January 2007 (Protocol Version 07/26/05)
- Protocol Version 07/26/05
- Toxicity Summary Dated 12/13/06
- 10/17/05: DMC Report
- Report of Studies Dated November 2005



#### **GOG-0204**

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

- Informed Consent for Protocol Version 07/26/06 [Per Sept. 06 CR]

#### **NSABP-B-34**

Continuing Review (CR) January 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/10/04)
- 01/29/07: CIRB Continuing Review Approval January 2007 (Protocol Version 06/10/04)
- 12/15/06: NSABP Cover Letter
- Protocol Version 06/10/04
- 10/20/06: DMC Minutes
- 04/07/06: DMC Minutes
- Study Progress Report Dated 12/31/05

#### **NSABP-B-35**

Continuing Review (CR) January 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/31/06)
- 02/08/07: CIRB Continuing Review Approval January 2007 (Protocol Version 05/31/06)
- 12/29/06: NSABP Cover Letter
- Protocol Version 05/31/06
- 10/20/06: DMC Minutes
- 04/07/06: DMC Minutes
- Study Progress Report Dated 12/31/05

#### **NSABP-B-42**

Continuing Review (CR) January 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/12/06)
- 01/29/07: CIRB Continuing Review Approval January 2007 (Protocol Version 07/12/06)
- Protocol Version 07/12/06



- Informed Consent for Protocol Version 07/12/06 [Per Jan. 07 CR]: Main Study
- Informed Consent for Protocol Version 07/12/06 [Per Jan. 07 CR]: Registration Program
- 12/15/06: NSABP Cover Letter

#### **RTOG-0214**

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 12/08/05)
- 02/01/07: CIRB Continuing Review Approval January 2007 (Protocol Version 12/08/05)
- 11/01/06: Continuing Review Notice for January 2007
- Protocol Version 12/08/05 (Per Amendment #4)
- Informed Consent for Protocol Version 12/08/05 [Per Jan. 07 CR]
- 06/16/06: DMC Minutes
- Report of Studies Dated June 2006

#### **RTOG-0522**

Note: There are two protocol version dates for Amendment #2 and they were approved independently.

Amendment Review: Amendment #2 (Protocol Version 01/08/07)

Documents Posted:

- 01/08/07: Change Memo
- 01/08/07: Summary of Changes
- CIRB Application Version 01/08/07
- Summary of CIRB Application Revisions Version 01/08/07
- 01/31/07: CIRB Amendment #2 Approval (Protocol Version 01/08/07)
- Protocol Version 01/08/07
- Informed Consent for Protocol Version 01/08/07

Amendment Review: Amendment #2 (Protocol Version 10/27/06)

Documents Posted:

- 10/27/06: Change Memo
- 10/27/06: Summary of Changes
- CIRB Application Version 10/27/06
- Summary of CIRB Application Revisions Version 10/27/06
- 12/15/06: CIRB Amendment #2 Approval (Protocol Version 10/27/06)
- Protocol Version 10/27/06



- Informed Consent for Protocol Version 10/27/06
- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Amendment #2 Review

## **Serious Adverse Events**

**Study: RTOG-0320**

**SAEs Posted: 2005001356 (1), 2006SP008904, 2006-07-1249 (4)**

**Study: RTOG-0525**

**SAEs Posted: 2006SP008904, 2006-07-1249 (4)**

**Study: SWOG S0124**

**SAEs Posted: 2006062325, 2006150262**

---

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 <mailto:ncicirbcontact@emmes.com>.