



## NCI Central IRB Study Activity Update

July 31, 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-AALL07P4**

Initial Review 2008 Approval  
Documents Posted:

- Protocol Version Date 03/14/08
- Protocol Version Date 03/14/08 - Highlighted Changes
- Protocol Version Date 12/03/07
- Protocol Version Date 12/03/07 - Highlighted Changes
- CIRB Application (Protocol Version Date 03/13/08)
- CIRB Application (Protocol Version Date 12/03/07)
- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Primary Reviewer 2 Comments
- 01/10/08: Primary Reviewer 3 Comments
- 01/10/08: Pharmacist Comments
- 04/08/08: CIRB Final Approval Letter (Protocol Version Date 03/14/08)
- 03/14/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 03/14/08)
- 01/23/08: CIRB Approval Pending Modification Letter (Protocol Version Date 12/03/07)
- 01/10/08: Minutes - Initial Review

## **Other Activity Posted:**

#### **ACOSOG-Z1031**

Amendment Review (AR): Amendment #5 Approval  
Documents Posted:

- CIRB Application (Protocol Version Date 05/07/08)
- CIRB Summary of CIRB Application Revisions (Protocol Version Date 05/07/08)
- CIRB Application (Protocol Version Date 04/07/08)
- CIRB Application (Protocol Version Date 03/07/08)
- CIRB Application (Protocol Version Date 02/04/08)



- CIRB Application (Protocol Version Date 11/16/07)
- 07/03/08: CIRB Amendment 5 Approval Letter (Protocol Version Date 05/07/08)
- 04/04/08: CIRB SAE 1921886 Review
- 03/07/08: ACOSOG Response to CIRB
- 03/06/08: CIRB Approval Pending Modification (Protocol Version Date 02/04/08)
- 02/04/08: ACOSOG Response to CIRB
- 02/03/08: CIRB Table of Amendment Review (Protocol Version Date 11/16/07)
- 01/17/08: SAE 1921886
- Protocol Version Date 05/07/08 (Per Am5)
- Protocol Version Date 05/07/08 (Highlighted)
- Protocol Version Date 04/07/08 (Highlighted)
- Protocol Version Date 03/07/08
- Protocol Version Date 03/07/08 (Highlighted)
- Protocol Version Date 02/04/08
- Protocol Version Date 02/04/08 (Highlighted)
- Protocol Version Date 11/16/07
- Protocol Version Date 11/16/07 (Highlighted)
- Informed Consent Document (Main) for Protocol Version 05/07/08 [Per Am5]
- Informed Consent Document (Genome) for Protocol Version Date 05/07/08 [Per Am5]
- Informed Consent Document (Supplemental) for Protocol Version Date 05/07/08 [Per Am5]
- 02/22/08: Primary Reviewer 1 Comments
- 02/22/08: Minutes - Group Response-Amendment 5 Review
- 01/04/08: Minutes - Amendment 5 Review

### **CALGB-50303**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/17/07)
- 07/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/17/08)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 04/17/07
- Informed Consent Document for Protocol Version Date 04/17/09 [Per Jun08 CR]
- 06/16/08: Primary Reviewer 1 Comments
- November 2007 - Study Summary



### **CALGB-90203**

Amendment Review (AR): Diet & Lifestyle Questionnaire  
Documents Posted:

- 07/15/08: CIRB Approval Letter - Diet & Lifestyle Questionnaire (Protocol Version Date 02/12/08)
- Comprehensive Diet and Lifestyle Survey

### **COG-AALL00331**

Continuing Review (CR): May 2008  
Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### **COG-AALL003B1**

Continuing Review (CR): May 2008  
Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### **COG-AALL0433**

Amendment Review (AR): Review of AALL0433 Family/Patient Letter regarding Temporary Study Enrollment Suspension  
Documents Posted:

- 07/22/08: Review of AALL0433 Family/Patient Letter regarding Temporary Study Enrollment Suspension
- 06/27/08: Patient/Family Letter

### **COG-AALL0434**

Continuing Review (CR): June 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/03/07)
- 07/17/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/03/07)
- 07/10/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/03/07)



- 07/07/08: CIRB Approval Pending Modification Letter (Protocol Version Date 08/03/07)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/03/07
- Informed Consent Document for Protocol Version Date 08/03/07: Part I - Induction Therapy
- Informed Consent Document for Protocol Version Date 08/03/07: Part II - Low Risk
- Informed Consent Document for Protocol Version Date 08/03/07: Part II - Intermediate Risk
- Informed Consent Document for Protocol Version Date 08/03/07: Part II - High Risk
- Informed Consent Document for Protocol Version Date 08/03/07: Optional Pharmacokinetic
- Informed Consent Document for Protocol Version Date 08/03/07: Part II - Induction Failure
- 05/14/08: Planned Safety Amendment
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

#### **COG-AALL0622**

Initial Review 2008

Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Primary Reviewer 2 Comments
- 05/08/08: Primary Reviewer 3 Comments
- 05/08/08: Minutes - Group Response to Initial Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-AALL03N1**

Continuing Review (CR): July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/03/07)
- 07/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/03/07)
- 06/05/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/03/07
- Informed Consent Document for Protocol Version Date 01/03/07
- 10/01/07: Study Progress Report



#### **COG-AALL05B1**

Initial Review 2006  
Documents Posted:

- 04/12/07: Primary Reviewer 1 Comments
- 04/12/07: Minutes - Review for Risk Determination

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-AALL00631**

Continuing Review (CR): May 2008  
Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-AALL06N1**

Continuing Review (CR): June 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/04/06)
- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 12/04/06)
- 07/11/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 12/04/06)
- 07/07/08: CIRB Approval Pending Modification Letter (Protocol Version Date 12/04/06)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 12/04/06
- Informed Consent Document for Protocol Version Date 12/04/06
- 02/04/08: Study Progress Report

#### **COG-AALL07P4**

Amendment Review (AR): Activation Amendment (Protocol Version Date 05/21/08)  
Documents Posted:

- CIRB Application (Protocol Version Date 05/21/08)
- 06/09/08: CIRB Approval of Activation Amendment Letter (Protocol Version Date 05/21/08)
- Protocol Version Date 05/21/08
- Protocol Version Date 05/21/08 - Highlighted Changes



- Informed Consent Document for Protocol Version Date 05/21/08

#### **COG-ABTR04B1**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/06/07)
- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/06/07)
- 07/08/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/06/07)
- 07/07/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/06/07)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/06/07
- Informed Consent Document for Protocol Version Date 02/06/07

Continuing Review (CR): Continuing Review September 2007

Documents Posted:

- 09/27/07: Primary Reviewer 1 Comments
- 09/27/07: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-ACCL04C2**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/27/08)
- 07/17/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/27/08)
- 07/16/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/27/08)
- 07/03/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/27/08)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/27/08
- Informed Consent Document for Protocol Version Date 02/27/08
- 02/04/08: Study Progress Report

#### **COG-ACCRN07**

Continuing Review (CR): June 2008



Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/19/07)
- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/19/07)
- 07/11/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 09/19/07)
- 06/07/08: CIRB Approval Pending Modification Letter (Protocol Version Date 09/19/07)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/19/07
- Assent Form Document for Protocol Version Date 09/19/07
- Informed Consent Document for Protocol Version Date 09/19/07 - Patient Consent
- Informed Consent Document for Protocol Version Date 09/19/07 - Parental Consent
- Information Sheet for ACCRN07 (Protocol Version Date 09/19/07)
- Permission Forms for ACCRN07 (Protocol Version Date 09/19/07)

**COG-ACNS0232**

Amendment Review (AR): Amendment #1 (Protocol Version Date 06/09/08)

Documents Posted:

- CIRB Application (Protocol Version Date 06/09/08)
- 07/10/08: CIRB Approval Letter (Protocol Version Date 06/09/08)
- 06/10/08: Change Memo (Protocol Version Date 06/09/08)
- Protocol Version Date 06/09/08
- Protocol Version Date 06/09/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 06/09/08

**COG-ACNS0423**

Continuing Review (CR): May 2008

Documents Posted:

- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**COG-ADVL0525**

Continuing Review (CR): May 2008

Documents Posted:



- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-AEWS0521**

**\*\*Temporarily Closed to Accrual by COG - Effective July 1, 2008\*\***

Amendment Review (AR): CIRB Acknowledgement of AEWS0521 Temporary Closure to Accrual  
Documents Posted:

- 07/14/08: CIRB Acknowledgement of AEWS0521 Temporary Closure to Accrual
- 07/11/08: AEWS0521 Temporary Suspension of Accrual

#### **COG-AHOD03P1**

Continuing Review (CR): Continuing Review August 2007  
Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-ANBL0322**

Continuing Review (CR): Continuing Review July 2008  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/28/07)
- 07/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/07)
- Protocol Version Date 03/28/07
- 02/04/08: Study Progress Report
- 10/25/07: DSMC Report

#### **COG-ANBL0421**

**\*\*Temporarily Closed to Accrual by COG - Effective July 18, 2008\*\***

Amendment Review (AR): CIRB Acknowledgement of Temporary Closure to Accrual



Documents Posted:

- 07/18/08: CIRB Acknowledgement of Temporary Closure to Accrual
- 07/18/08: Temporary Closure of Study ANBL0421

**COG-AOST06B1**

Amendment Review (AR): Activation Amendment #1

Documents Posted:

- 04/12/07: Minutes - Review for Age of Assent Determination

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**COG-ARAR0331**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/25/05)
- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/25/05)
- 07/07/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/25/05)
- 07/03/08: CIRB Approval Pending Modification Letter (Protocol Version Date 05/25/05)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/25/05
- Informed Consent Document for Protocol Version Date 05/25/05
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

Continuing Review (CR): Continuing Review August 2007

Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

**COG-AREN0321**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/20/06)



- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/20/06)
- 07/10/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/20/06)
- 07/07/08: CIRB Approval Pending Modification Letter (Protocol Version Date 11/20/06)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/20/06
- Informed Consent Document for Protocol Version Date 11/20/06: Regimen DD-4A
- Informed Consent Document for Protocol Version Date 11/20/06: Observation
- Informed Consent Document for Protocol Version Date 11/20/06: Regimen I
- Informed Consent Document for Protocol Version Date 11/20/06: Regimen UH1
- Informed Consent Document for Protocol Version Date 11/20/06: Window Therapy
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

#### **COG-AREN03B2**

Amendment Review (AR): Amendment #3 (Protocol Version Date 05/23/08)  
Documents Posted:

- CIRB Application (Protocol Version Date 05/23/08)
- CIRB Application (Protocol Version Date 02/11/08)
- 06/30/08: CIRB Amendment #3 Approval Letter (Protocol Version Date 05/23/08)
- 05/23/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/23/08)
- 03/24/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/11/08)
- 02/11/08: Change Memo (Protocol Version Date 02/11/08)
- Protocol Version Date 05/23/08
- Protocol Version Date 05/23/08 - Highlighted Changes
- Protocol Version Date 02/11/08
- Protocol Version Date 02/11/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 05/23/08

#### **COG-ARET0331**

Continuing Review (CR): Continuing Review August 2007  
Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Minutes - Continuing Review



**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-ARET0332**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/05/06)
- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/05/06)
- 07/08/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 09/05/06)
- 07/07/08: CIRB Approval Pending Modification Letter (Protocol Version Date 09/05/06)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/05/06
- Informed Consent Document for Protocol Version Date 09/05/06: Observation Arm
- Informed Consent Document for Protocol Version Date 09/05/06: Chemotherapy Arm
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

#### **COG-ARST0531**

Continuing Review (CR): Continuing Review August 2007

Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **COG-D9902**

Amendment Review (AR): Amendment Review #A

Documents Posted:

- 04/12/07: Minutes - Review for Age of Assent Determination

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

#### **ECOG-E4A03**

Amendment Review (AR): Addendum #7 (Protocol Version Date 03/27/08)

Documents Posted:



- 03/27/08: Change Memo (Protocol Version Date 03/27/08)
- 07/23/08: CIRB Acknowledgement of Posting Addendum 7 (Protocol Version Date 03/27/08)
- 06/23/08: CIRB Addendum 7 Approval Letter (Protocol Version Date 03/27/08)
- Protocol Version Date 03/27/08 (Per Add 7)
- 06/06/08: Minutes - Addendum 7 Review

#### **ECOG-E1105**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/09/07)
- 07/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/09/07)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 11/09/07 [Per Jun08 CR]
- Informed Consent Document for Protocol Version Date 11/09/07 [Per Jun08 CR]
- 06/16/08: Primary Reviewer 1 Comments
- Study Summary - November 2007
- 09/24/07: DMC Recommendations

#### **ECOG-E1899**

Continuing Review (CR): July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/16/04)
- 07/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/16/06)
- 06/06/08: Continuing Review Reminder Notice (Protocol Version Date 06/16/04)
- Protocol Version Date 06/16/04 (Per CR Jul 08)
- June 2005 - Study Summary
- 11/02/04: DMC Meeting Report

#### **ECOG-E2805**

Continuing Review (CR): June 2008

Documents Posted:

- 06/06/08: Minutes - Continuing Review

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**



### **ECOG-E3200**

**\*\*COMPLETED (No Further Activity Being Conducted) as of April 20, 2007\*\***

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/07/07)
- 07/22/08: CIRB Closure of ECOG E3200 Due to Study Completion
- Study Summary - November 2004

### **ECOG-E3805**

Amendment Review (AR): Addendum #3 (Protocol Version Date 03/13/08)

Documents Posted:

- 07/22/08: CIRB Acknowledgement of Posting - Addendum 3 (Protocol Version Date 03/13/08)

**Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.**

### **ECOG-E4599**

Continuing Review (CR): July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/19/07)
- 07/21/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/19/07)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/19/07 [Per Jul08 CR]
- 12/14/06: New England Journal of Medicine Abstract
- Study Summary - June 2006
- DMC Meeting Report - 3/9/05 & 4/6/05

### **ECOG-E5103**

Amendment Review (AR): Update #3 (Protocol Version Date 05/28/08)

Documents Posted:

- 05/28/08: Change Memo (Protocol Version Date 05/28/08)
- CIRB Application (Protocol Version Date 05/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/28/08)
- 07/23/08: CIRB Acknowledgement of Posting of Update 3 (Protocol Version Date 05/28/08)
- 07/21/08: CIRB Update 3 Approval Letter (Protocol Version Date 05/28/08)
- Protocol Version Date 05/28/08 [Per Up 3]
- Informed Consent Document for Protocol Version Date 05/28/08 [Per Up 3]



- 06/27/08: Primary Review 1 Comments

#### **ECOG-E6201**

**\*\*COMPLETED (No Further Activity Being Conducted) as of February 4, 2008\*\***

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/07/07)
- 07/28/08: CIRB Closure Due to Study Completion Letter
- Protocol Status Update

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

Amendment Review (AR): Addendum #3 (Protocol Version Date 03/21/08)

Documents Posted:

- 03/21/08: Change Memo (Protocol Version Date 03/21/08)
- CIRB Application (Protocol Version Date 03/21/08)
- Summary of CIRB Application Revisions (Protocol Version Date 03/21/08)
- 07/25/08: CIRB Addendum 3 Approval Letter (Protocol Version Date 03/21/08)
- Protocol Version Date 03/21/08 [Per Add 3]
- Informed Consent Document for Protocol Version 03/21/08
- 05/02/08: Primary Review 1 Comments
- 05/02/08: Primary Review 2 Comments
- 05/02/08: Minutes - Addendum 3 Review

#### **GOG-0219**

Continuing Review (CR): July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/22/08)
- 07/21/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/22/08)
- 07/01/08: Continuing Review Reminder Notice
- Protocol Version Date 05/22/08
- Informed Consent Document for Protocol Version Date 05/22/08
- Study Summary - January 2008
- 01/26/08: DSMB Minutes

#### **NSABP-B-36**

Amendment Review (AR): CIRB Acknowledgement of Upcoming Closure to Accrual

Documents Posted:

**\*\* Final Day to New Accrual is July 25, 2008 at 4:00 p.m. EST \*\***



- 07/18/08: CIRB Acknowledgement of Upcoming Closure to Accrual

#### **RTOG-0214**

Continuing Review (CR): July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/01/07)
- 07/21/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/01/07)
- 06/06/08: Continuing Review Reminder Notice
- Protocol Version Date 10/01/07 (Per CR 08)
- Status Summary - June 2008
- 01/11/08: DMC Minutes
- 10/01/07: Change Memo

#### **RTOG-0320**

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/08/07)
- 06/18/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/08/08)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/08/07 [Per Jun08 CR]
- Informed Consent Document for Protocol Version Date 05/08/07 [Per Jun08 CR]
- 06/16/08: Primary Reviewer 1 Comments
- Study Summary - January 2008
- 01/11/08: DMC Minutes

#### **RTOG-0415**

Continuing Review (CR): July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/03/07)
- 07/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 12/03/07)
- 06/06/08: Continuing Review Reminder Notice (Protocol Version Date 12/03/07)
- Protocol Version Date 12/03/07 (Per CR Jul 08)
- Informed Consent Document for Protocol Version Date 12/03/07 [Per CR Jul 08]
- Informed Consent Document [Tissue] for Protocol Version Date 12/03/07 [Per CR Jul 08]
- 01/11/08: DMC Minutes



- Study Summary - January 2008
- 12/03/07: Change Memo (Amendment 2) Protocol Version Date 12/03/07

#### **RTOG-0521**

Amendment Review (AR): Amendment #4 Approval  
Documents Posted:

- 05/15/08: Change Memo (Protocol Version Date 05/15/08)
- CIRB Application (Protocol Version Date 05/15/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/15/08)
- 06/30/08: CIRB Amendment 4 Approval Letter (Protocol Version Date 05/15/08)
- Protocol Version Date 05/15/08 [Per Am4]
- Protocol Version Date 05/15/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 05/15/08 [Per Am4]
- Informed Consent Document (Tissue) for Protocol Version Date 05/15/08 [Per Am4]

#### **SWOG-S0023**

Continuing Review (CR): July 2008  
Documents Posted:

- 06/12/08: CIRB Closure Due to Study Completion

**\*\*COMPLETED (No Further Activity Being Conducted) as of June 12, 2008\*\***

#### **SWOG-S0502**

Amendment Review (AR): Revision #1 Approval  
Documents Posted:

- 04/24/08: Change Memo (Protocol Version Date 04/24/08)
- CIRB Application (Protocol Version Date 04/24/08)
- Summary of CIRB Application Revisions (Protocol Version Date 04/24/08)
- 07/23/08: CIRB Acknowledgement of Posting - Revision 1 (Protocol Version Date 04/24/08)
- 06/23/08: CIRB Revision 1 Approval Letter (Protocol Version Date 04/24/08)
- Protocol Version Date 04/24/08 [Per Rev 1]
- Informed Consent Document for Protocol Version Date 04/24/08 [Per Rev 1]

#### **SWOG-S0600**

Amendment Review (AR): Revision #1 Approval  
Documents Posted:



- 04/10/08: Change Memo (Protocol Version 04/10/08)
- CIRB Application (Protocol Version Date 04/10/08)
- Summary of CIRB Application Revisions (Protocol Version Date 04/10/08)
- 07/23/08: CIRB Acknowledgement of Revision 1 Posting (Protocol Version Date 04/10/08)
- 06/05/08: CIRB Revision 1 Approval Letter (Protocol Version Date 04/10/08)
- Protocol Version Date 04/10/08 [Per Rev 1]
- Informed Consent Document for Protocol Version Date 04/10/08 [Per Rev 1]

## **Corrections to Previous Study Activity Updates**

### **ECOG-E4A03**

Amendment Review (AR): Addendum #5 Approval 06/02/06 Protocol Version Date 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

**Correction: Addendum 5 was not added to the Study Activity Update when posted on the NCI/CIRB Web Site in June 2006. It is included now for your convenience.**

### **ECOG-E2805**

Continuing Review (CR): June 2008

Correction: The informed consent document formatting was corrected.

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

Amendment Review (AR): Addendum #5 (Protocol Version Date 11/14/07)

Correction: The title of Amendment 5 was changed to Update 3 for consistency in posting.



**RTOG-0436**

Initial Review 2007 Approval  
Documents Posted:

- 07/18/08: CIRB Acknowledgement of Activation (Protocol Version Date 03/28/08)

Correction: Acknowledgement of Receipt for Activation added to correspondence of Initial Review.

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).