



## NCI Central IRB Website Postings Summary

January 1, 2010

The NCI CIRB Operations Office is distributing this Website Postings Summary to all CIRB sites to provide a summary of the review documents posted to the CIRB website (<http://www.ncicirb.org/>) since the last update. Please note: for a complete listing of all documents pertaining to a specific review, visit the study-specific webpage.

Although these summary posting updates are provided on the 1<sup>st</sup> and 15<sup>th</sup> of every month, the CIRB Operations Office posts review documents and updates to the CIRB website on a daily basis.

All review documents are posted on the study-specific webpages. All notices are posted under the "What's New" section of the CIRB homepage. If you are unsure of your username and password or have difficulty accessing the website, please email [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) or call the CIRB HelpDesk toll-free at 888-657-3711.

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### CIRB Notices

- NONE

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### Study-Specific Review Documents Recently Posted

### **Posted Documents Related to Initial Reviews:**

The review documents listed below pertain to initial CIRB reviews. These new studies are now available for facilitated review.



## **Adult Studies**

Documents Posted:

- NONE

## **Pediatric Studies**

### **COG-ANBL0931**

Initial Review (IR): 2009

Documents Posted:

- Protocol
  - Protocol Version Date 11/12/09
  - Protocol Version Date 11/12/09 - Highlighted Changes
  - Protocol Version Date 07/22/09
  - Protocol Version Date 07/22/09 - Highlighted Changes
- Informed Consent
  - Informed Consent Document for Protocol Version Date 11/12/09
- CIRB Application
  - CIRB Application (Protocol Version Date 11/12/09)
  - CIRB Application (Protocol Version Date 07/22/09)
- Primary Reviews
  - 09/10/09: Primary Reviewer 1 Comments
  - 09/10/09: Primary Reviewer 2 Comments
  - 09/10/09: Primary Reviewer 3 Comments
  - 09/10/09: Statistician Reviewer Comments
- Correspondence
  - 12/21/09: COG Activation of ANBL0931 Memo
  - 11/25/09: CIRB Final Approval Letter of ANBL0931 (Protocol Version Date 11/12/09)
  - 11/12/09: COG Response Letter (Protocol Version Date 07/22/09)
  - 09/23/09: CIRB Approval Pending Modification Letter of Initial Review of ANBL0931 (Protocol Version Date 07/22/09)
- Minutes
  - 09/10/09: Minutes - Initial Review



### COG-AHOD0831

Initial Review (IR): 2009

Documents Posted:

- Correspondence
  - 12/15/09: CIRB Acknowledgement of Activation of AHOD0831 Memo

**Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.**

### Posted Documents Related to Amendment Reviews:

#### Adult Studies

### CALGB-10501

**\*\*UPCOMING Closure to Accrual - effective January 5, 2010\*\***

Amendment Review (AR): CIRB Acknowledgement - Closure to Accrual

Documents Posted:

- Correspondence
  - 12/21/09: CIRB Acknowledgment of Closure to Accrual
  - 12/15/09: CALGB Closure Memo

### CALGB-90206

Amendment Review (AR): Update #10 (Protocol Version Date 11/19/09)

Documents Posted:

- Amendments
  - CALGB Change Memo (Protocol Version Date 11/19/09)
- Correspondence
  - 12/15/09: CALGB Monthly Update Extract
  - 12/02/09: CIRB Update 10 Approval Letter (Protocol Version Date 11/19/09)
- Protocol
  - Protocol Version Date 11/19/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 11/19/09 [Up10]



### **CALGB-100104**

Amendment Review (AR): CIRB Acknowledgement - CALGB 100104 Unblinding

Documents Posted:

- Correspondence
  - 12/23/09: CIRB Acknowledgement of CALGB 100104-ECOG 100104 Unblinding
  
- Support Documents
  - CALGB Unblind Instructions from November 2009 - CALGB DSMC Required Action
  - CALGB Continuation of Therapy (Unblinding) Form
  - CALGB Participant Notification Letter
  - CALGB Physician Notification Letter

### **ECOG-E5103**

Amendment Review (AR): Addendum #5 (Protocol Version Date 12/11/09) & Re-Opening to Accrual

Documents Posted:

- Amendments
  - ECOG Change Memo (Protocol Version Date 12/11/09)
  
- CIRB Application
  - CIRB Application (Protocol Version Date 12/11/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 12/11/09)
  
- Correspondence
  - 12/22/09: CIRB Acknowledgement of ECOG E5103 Re-opening to Accrual
  - 12/21/09: ECOG Activation Notice Extract
  - 12/18/09: ECOG Re-Opening to Accrual Memo
  - 12/17/09: CIRB Addendum 5 Approval Letter (Protocol Version Date 12/11/09)
  
- Protocol
  - Protocol Version Date 12/11/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 12/11/09 [Add5]



### **GOG-0219**

**\*\*Closed to Accrual - effective September 1, 2009\*\***

Amendment Review (AR): CIRB Approval - Permanent Closure

Documents Posted:

- Correspondence
  - 12/21/09: CIRB Approval Letter Permanent Closure
  - 12/07/09: GOG Permanent Closure Memo
  
- Protocol
  - Protocol Version Date 06/05/09

### **GOG-0249**

Amendment Review (AR): Update 12/16/09 (Protocol Version Date 10/09/09)

Documents Posted:

- Amendments
  - GOG Change Memo (Protocol Version Date 10/09/09)
  
- Correspondence
  - 12/28/09: CIRB Approval Letter Update of 12/16/09 (Protocol Version Date 10/09/09)
  
- Protocol
  - Protocol Version Date 10/09/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 10/09/09 [Up121609]

### **GOG-0250**

Amendment Review (AR): Amendment #1 (Protocol Version Date 11/30/09)

Documents Posted:

- Amendments
  - GOG Change Memo (Protocol Version Date 11/30/09)
  
- CIRB Application
  - CIRB Application (Protocol Version Date 11/30/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 11/30/09)
  
- Correspondence
  - 12/9/09: CIRB Approval Letter Amendment 1 (Protocol Version Date 11/30/09)



- Protocol
  - Protocol Version Date 11/30/09
  - Protocol Version Date 11/30/09 - Highlighted Changes
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 11/30/09 [Am1]
  - CIRB's Informed Consent Document for Protocol Version Date 11/30/09 - Highlighted Changes

#### **GOG-0258**

Amendment Review (AR): Update 12/14/09 (Protocol Version Date 09/29/09)

Documents Posted:

- Amendments
  - GOG Change Memo (Protocol Version Date 09/29/09)
  
- Correspondence
  - 12/28/09: CIRB Approval Letter Update of 12/14/09 (Protocol Version Date 09/29/09)
  
- Protocol
  - Protocol Version Date 09/29/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 09/29/09 [Up12/14/09]

#### **NCCTG-N0147**

Amendment Review (AR): Addendum #11 (Protocol Version Date 11/12/09)

Documents Posted:

- Amendments
  - NCCTG Change Memo (Protocol Version Date 11/12/09)
  
- CIRB Application
  - CIRB Application (Protocol Version Date 11/12/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 11/12/09)
  
- Correspondence
  - 12/14/09: NCCTG Activation Notice Extract
  - 12/01/09: CIRB Addendum 11 Approval Letter (Protocol Version Date 11/12/09)



- Protocol
  - Protocol Version Date 11/12/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 11/12/09 [Add11]

Amendment Review (AR): CIRB Acknowledgement - Closure Unanticipated Problem Determination

Documents Posted:

- Correspondence
  - 12/21/09: CIRB Unanticipated Problem Determination Letter
  - 11/30/09: CIRB Acknowledgement - Permanent Closure to Accrual, Dear Patient & Dear Doctor Letters, and DMC Minutes
  - 11/25/09: NCCTG Notice of Status Change
- Support Documents
  - 11/25/09: Participant Notification Letter - Permanent Closure to Accrual
  - 11/25/09: Physician Notification Letter - Permanent Closure to Accrual
  - 11/24/09: Minute item for NCCTG DMC Conference Call
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
  - 12/17/09: Primary Reviewer 2 Comments

#### **SWOG-S0777**

Amendment Review (AR): Revision #5 (RRA) Protocol Version Date 11/02/09

Documents Posted:

- Amendments
  - SWOG Change Memo (Protocol Version Date 11/02/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 11/02/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 11/02/09)
- Correspondence
  - 12/15/09: SWOG Activation Notice Extract
  - 11/06/09: CIRB Revision 5 Approval Letter (Protocol Version Date 11/02/09)



- Support Documents
  - OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol
  - Protocol Version Date 11/02/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 11/02/09 [Rev5]
  - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 11/02/09 [Rev5]

## **Pediatric Studies**

### **COG-ACNS0333**

**\*\*Temporary Suspension of Accrual by COG - Effective December 4, 2009\*\***

Amendment Review (AR): **CIRB Acknowledgement of ACNS0333 Temporary Suspension of Accrual Memo and Family/Patient Letter (Dated 12/04/2009) - Unanticipated Problem Determination**

Documents Posted:

- Correspondence
  - 12/22/2009: CIRB Acknowledgement of ACNS0333 Temporary Suspension Memo and Family/Patient Letter
  - 12/18/09: CIRB Report of an Unanticipated Problem Letter
  - 12/10/09: COG Participant Notification Letter - ACNS0333 Temporary Suspension
  - 12/04/09: COG ACNS0333 Temporary Suspension of Accrual Pending Assessment of Toxicities

### **COG-ADVL0221**

**\*\*Temporary Closure of the Rhabdomyosarcoma Stratum by COG of ADVL0221 - Effective December 2, 2009\*\***

Amendment Review (AR): **Temporary Closure of the Rhabdomyosarcoma Stratum (12/02/2009)**

Documents Posted:

- Correspondence
  - 12/15/09: CIRB Acknowledgement of Temporary Closure of the Rhabdomyosarcoma Stratum Memo
  - 12/02/09: COG Memo - Temporary Closure of Rhabdomyosarcoma Stratum



### **COG-ADVL06B1**

**\*\*Stratum 3 Closed to Accrual by COG – Effective December 4, 2009\*\***

Amendment Review (AR): **CIRB Acknowledgement of COG ADVL06B1 Stratum Closures (12/04/2009)**

Documents Posted:

- Correspondence
  - 12/15/09: CIRB Acknowledgement - ADVL06B1 Stratum 3, Stratum 5 and Stratum 7 Closures
  - 12/04/09: COG Notice - ADVL06B1 Stratum 3, Stratum 5 and Stratum 7 Closures

### **COG-ANBL0931**

Amendment Review (AR): Activation Amendment #1 (Protocol Version Date 12/17/2009)

Documents Posted:

- Amendments
  - 12/17/09: COG Change Memo (Protocol Version Date 12/17/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 12/17/09)
- Correspondence
  - 12/18/09: CIRB Approval of COG-ANBL0931 Activation Amendment #1 (Protocol Version Date 12/17/09)
- Protocol
  - Protocol Version Date 12/17/09
  - Protocol Version Date 12/17/09 - Highlighted Changes
- Informed Consent
  - Informed Consent Document for Protocol Version Date 12/17/09 [Per Amd. 2]

## **Posted Documents Related to Continuing Reviews:**

### **Adult Studies**

#### **CALGB-40502**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes



- 12/03/09: Minutes – Continuing Review

**Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.**

#### **CALGB-80101**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
  - 12/03/09: Minutes – Continuing Review

**Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.**

#### **CALGB-90203**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 07/17/08)
- Correspondence
  - 12/21/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/17/08)
  - 11/03/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 07/17/08
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/17/08 [CR09]
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
- Support Documents
  - June 2009 - DSMB
  - June 2009 - Study Summary



#### **CALGB-100104**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
  - 12/03/09: Minutes – Continuing Review

**Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.**

#### **ECOG-E1305**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 10/06/09)
- Correspondence
  - 12/21/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/06/09)
  - 11/02/2009: Continuing Review Reminder
- Protocol
  - Protocol Version Date 10/06/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 10/06/09 [CR09]
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
- Support Documents
  - November 2009 - Study Summary
  - October 2009 - ECOG DMC Recommendations

#### **GOG-0204**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
  - 12/03/09: Minutes – Continuing Review



**Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.**

#### **NCCTG-N0723**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 08/24/09)
  
- Correspondence
  - 12/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/24/09)
  - 11/03/09: Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 08/24/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 08/24/09 [CR09]
  - CIRB's Informed Consent Document (Instructions for Local institutions) for Protocol Version Date 08/24/09 [CR09]
  
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
  
- Support Documents
  - 09/23/09: NCCTG DMC Adverse Events Report
  - 05/13/09: NCCTG DMC Adverse Events Report

#### **RTOG-0129**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 08/06/08)
  
- Correspondence
  - 12/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/08)
  - 11/03/09: Continuing Review Reminder Notice



- Protocol
  - Protocol Version Date 08/06/08
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 08/06/08 [CR09]
- Support Documents
  - June 2009 - DMC Meeting Minutes
  - June 2009 - Study Summary
  - Report of efficacy and toxicity, K Ang, et al
  - Survival Outcomes by Tumor Human, Gillison, M., J. Harris, et al. (2009).

### **SWOG-S0307**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
  - 12/03/09: Minutes – Continuing Review

**Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.**

### **SWOG-9007**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 06/24/09)
- Correspondence
  - 12/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/24/09)
  - 11/03/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 06/24/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 06/24/09 [CR09]
  - CIRB's Informed Consent Document - Instructions (Protocol Version Date 06/24/09) [CR09]



- Support Documents
  - 12/21/07: American Society of Hematology Abstract
  - October 2009 - Study Summary
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments

### **SWOG-S0309**

Continuing Review (CR): Continuing Review December 2009

#### Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 02/12/07 )
- Correspondence
  - 12/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
  - 11/03/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 02/12/07
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
- Support Documents
  - October 2007 - Study Summary

### **SWOG-S0337**

Continuing Review (CR): Continuing Review December 2009

#### Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 08/10/09)
- Correspondence
  - 12/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/10/09)
  - 11/03/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 08/10/09



- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 08/10/09 [CR09]
  - CIRB's Informed Consent Document (Instructions for Local institutions) for Protocol Version Date 08/10/09 [CR09]
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
- Support Documents
  - 10/23/09: DSMC Meeting Minutes
  - October 2009 - Study Summary

### **SWOG-S9910**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- CIRB Application
  - CIRB Continuing Review Application (Protocol Version Date 05/26/09)
- Correspondence
  - 12/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/26/09)
  - 11/03/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 05/26/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 05/26/09 [CR09]
  - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 05/26/09 [CR09]
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments
- Support Documents
  - October 2009 - Study Summary

### **SWOG-S9925**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 01/06/09)
- Correspondence
  - 12/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/06/09)
  - 11/03/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 01/06/09
- Primary Reviews
  - 12/17/09: Primary Reviewer 1 Comments

## **Pediatric Studies**

### **COG-AALL0331**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 03/25/09)
- Correspondence
  - 12/28/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/25/09)
  - 12/23/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 03/25/09)
  - 12/16/09: CIRB Approval Pending Modification Letter (Protocol Version Date 03/25/09)
  - 10/06/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 03/25/09
- Informed Consent
  - Informed Consent Document for Protocol Version Date 03/25/09: Part I - Induction Therapy
  - Informed Consent Document for Protocol Version Date 03/25/09: Standard Risk - Average
  - Informed Consent Document for Protocol Version Date 03/25/09: Standard Risk - Low



- Informed Consent Document for Protocol Version Date 03/25/09: Treatment Changes
- Informed Consent Document for Protocol Version Date 03/25/09: Standard Risk - High
  
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
  
- Support Documents
  - 03/09/09: DSMC Report - Spring 2009
  - 11/01/08: Study Progress Report - Spring 2009

#### **COG-AALL06N1**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 07/08/09)
  
- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/08/09)
  - 11/04/09: CIRB Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 07/08/09
  
- Informed Consent
  - Informed Consent Document for Protocol Version Date 07/08/09 [Per Dec. 09 CR] - Sites Participating In MRI With DTI Project
  - Informed Consent Document for Protocol Version Date 07/08/09 [Per Dec. 09 CR] - Sites NOT Participating In MRI With DTI Project
  
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
  
- Support Documents
  - 05/01/09: Study Progress Report - Fall 2009

#### **COG-AAML0531**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 07/14/09)
- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/14/09)
  - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 07/14/09
- Informed Consent
  - Informed Consent Document for Protocol Version Date 07/14/09 [Per Dec. 09 CR] - Parental Permission
  - Informed Consent Document for Protocol Version Date 07/14/09 [Per Dec. 09 CR] - Additional Bone Marrow
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
- Support Documents
  - 03/20/09: DSMC Report - Spring 2009
  - 11/01/08: Study Progress Report - Spring 2009

#### **COG-ADVL0525**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 05/07/08)
- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/07/08)
  - 10/06/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 05/07/08
- Informed Consent
  - Informed Consent Document for Protocol Version Date 05/07/08 [Per Dec. 09 CR]
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments



- Support Documents
  - 05/01/09: Study Progress Report - Fall 2009
  - 03/24/09: DSMC Report - Spring 2009

#### **COG-AEWS0521**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 10/13/08)
- Correspondence
  - 12/23/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/13/08)
  - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 10/13/08
- Informed Consent
  - Informed Consent Document for Protocol Version Date 10/13/08 [Per Dec. 09 CR] - Feasibility
  - Informed Consent Document for Protocol Version Date 10/13/08 [Per Dec. 09 CR] - Randomized Study
- Support Documents
  - 10/12/09: DSMC Report - Fall 2009
  - 05/01/09: Study Progress Report - Fall 2009

#### **COG-AEWS07P1**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 10/12/07)
- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/12/07)
  - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 10/12/07



- Informed Consent
  - Informed Consent Document for Protocol Version Date 10/12/07 [Per Dec. 09 CR]
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
- Support Documents
  - 10/23/09: DSMC Report - Fall 2009
  - 05/01/09: Study Progress Report - Fall 2009
  - 03/19/09: DSMC Report - Spring 2009

#### **COG-ANBL0421**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 06/21/07)
- Correspondence
  - 12/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/21/07)
  - 10/06/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 06/21/07
- Informed Consent
  - Informed Consent Document for Protocol Version Date 06/21/07 [Per Dec. 09 CR]
- Support Documents
  - 11/01/08: Study Progress Report - Spring 2009
  - 10/07/08: DSMC Report - Fall 2008

#### **COG-AREN0321**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 09/30/09)



- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/30/09)
  - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 09/30/09
- Informed Consent
  - Informed Consent Document for Protocol Version Date 09/30/09 [Per Dec. 09 CR] - Observation
  - Informed Consent Document for Protocol Version Date 09/30/09 [Per Dec. 09 CR] - Regimen 1
  - Informed Consent Document for Protocol Version Date 09/30/09 [Per Dec. 09 CR] - Regimen DD-4A
  - Informed Consent Document for Protocol Version Date 09/30/09 [Per Dec. 09 CR] - Regimen UH1
  - Informed Consent Document for Protocol Version Date 09/30/09 [Per Dec. 09 CR] - Window Therapy
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
- Support Documents
  - 10/12/09: DSMC Report - Fall 2009
  - 05/01/09: Study Progress Report - Fall 2009

### **COG-ARET0331**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 09/14/07)
- Correspondence
  - 12/23/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/14/07)
  - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 09/14/07
- Informed Consent
  - Informed Consent Document for Protocol Version Date 09/14/07 [Per Dec. 09 CR]



- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
  
- Support Documents
  - 10/12/09: DSMC Report - Fall 2009
  - 05/01/09: Study Progress Report - Fall 2009

#### **COG-ARET0332**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 08/03/09)
  
- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/03/09)
  - 11/04/09: CIRB Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 08/03/09
  
- Informed Consent
  - Informed Consent Document for Protocol Version Date 08/03/09 [Per Dec. 09 CR] - Observation Arm
  - Informed Consent Document for Protocol Version Date 08/03/09 [Per Dec. 09 CR] - Chemotherapy Arm
  
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
  
- Support Documents
  - 10/12/09: DSMC Report - Fall 2009
  - 05/01/09: Study Progress Report - Fall 2009

#### **COG-ARST0531**

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 08/20/09)



- Correspondence
  - 12/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/20/09)
  - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 08/20/09
- Informed Consent
  - Informed Consent Document for Protocol Version Date 08/20/09 [Per Dec. 09 CR]
- Primary Reviews
  - 12/10/09: Primary Reviewer 1 Comments
- Support Documents
  - 10/12/09: DSMC Report - Fall 2009
  - 05/01/09: Study Progress Report - Fall 2009

## **Serious Adverse Events Posted**

### **Adult Studies**

<b><u>SAEs Posted:</u></b> 1203233 1498428 1871314	<b>CALGB 100104</b>
<b><u>SAEs Posted:</u></b> 1168449 1613977	<b>CALGB 30607</b>
<b><u>SAEs Posted:</u></b> 1498428 1871314	<b>ECOG E1A05</b>



**ECOG E1A06**

**SAEs Posted:**

**1498428**

**1871314**

**ECOG E2805**

**SAEs Posted:**

**1168449**

**1613977**

**ECOG E2902**

**SAE Posted:**

**1320161 FU2**

**ECOG E2905**

**SAE Posted:**

**1871314**

**ECOG E4A03**

**SAE Posted:**

**1871314**

**ECOG E5204**

**SAEs Posted:**

**1279067**

**1293580 FU1**

**1333814 FU1**

**1438181 FU2**

**1613977**

**1687519 FU1**

**1833568 FU1**

**1836781 FU1**

**GOG 0218**

**SAEs Posted:**

**1133874 FU1**

**1158823 FU1**

**1192440**

**1202538**



1232396  
1232396 FU1  
1257729  
1257729 FU1  
1279067  
1293580 FU1  
1314985 FU1  
1329128 FU1  
1333814  
1333814 FU1  
1360351 FU1  
1390754  
1390754 FU1  
1392926  
1438181 FU2  
1613977  
1687519 FU1  
1718620  
1718620 FU1  
1718620 FU1-2<sup>nd</sup>  
1809441 FU1  
1833568 FU1  
1836781 FU1  
1881593 FU1  
1950915  
1968432 FU1  
1987521 FU1  
1994045 FU1

**NCIC CTG MA.27**

**SAE Posted:**  
10000536

**NSABP B-40**

**SAE Posted:**  
IT200907004289

**RTOG 0436**

**SAEs Posted:**  
08-02-14699 FU3  
08-02-14863 FU2  
08-02-15541 FU4  
09-02-15982 FU2  
09-02-16131 FU4



09-02-16382 FU3  
09-02-16443 FU8  
09-02-16482 FU3  
09-02-16791 FU2  
09-02-16791 FU4  
09-02-17088 FU2  
09-02-17282 FU1  
09-02-17337 FU1  
09-02-17337 FU3  
09-02-17337 FU4  
09-02-17423 FU2  
09-02-17423 FU3  
09-02-17429 FU1  
09-02-17430 FU1  
09-02-17431 FU1  
09-02-17446  
09-02-17446 FU1  
09-02-17508 FU1  
09-02-17588  
09-02-17698 FU1  
09-02-17717  
09-02-17717 FU1  
09-02-17718  
09-02-17718 FU1  
09-02-17763 FU1  
09-02-17763 FU2  
09-02-17843 FU1  
09-02-17854  
09-02-17883 FU1  
09-02-17883  
09-02-17971  
09-02-17988 FU1  
09-02-17988

**RTOG 0617**

**SAEs Posted:**

09-02-16043 FU8  
09-02-16382 FU3  
09-02-16791 FU2  
09-02-17088 FU2  
09-02-17337 FU1  
09-02-17508 FU1  
09-02-17698 FU1



**RTOG 0825**

**SAEs Posted:**

1232396 FU1  
1293580 FU1  
1438181 FU2  
1613977

**SWOG S0307**

**SAEs Posted:**

200926222 SU155  
200927870 SU156  
200927923 SU157

**SWOG S0502**

**SAEs Posted:**

1232396 FU1  
1257729 FU1  
1293580 FU1  
1314985 FU1  
1329128 FU1  
1438181 FU2  
1613977  
1994045 FU1

**SWOG S0518**

**SAEs Posted:**

1232396 FU1  
1257729 FU1  
1279067  
1293580 FU1  
1314985 FU1  
1329128 FU1  
1392926 FU1  
1419144 FU1  
1438181 FU2  
1613977  
1687519 FU1  
1710309  
1718620 FU1 - follow-up 1  
1720941 FU1  
1833568 FU1



1836781 FU1  
1839475 FU1  
1857033  
1950915 FU1  
1994045 FU1

### SWOG S0600

#### SAEs Posted:

1232396 FU1  
1257729 FU1  
1279067  
1314985 FU1  
1329128 FU1  
1392926 FU1  
1438181 FU2  
1613977  
1687519 FU1  
1710309  
1718620 FU1 - follow-up 1  
1720941 FU1  
1833568 FU1  
1836781 FU1  
1839475 FU1  
1994045 FU1

#### Pediatric Studies

None posted during this period.

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#### Corrections to Previous Postings

#### Adult Studies

- NONE



## **Pediatric Studies**

- NONE

If review of this Website Postings Summary has prompted any questions, please forward them to the NCI CIRB\_Operations Office Helpdesk at [NCICIRBContact@emmes.com](mailto:NCICIRBContact@emmes.com) or call the CIRB HelpDesk toll-free at 1-(888) 657-3711.