



## NCI Central IRB Website Postings Summary September 15, 2009

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**

##### **GOG-0258**

Initial Review (IR): 2009

Documents Posted:

- Minutes
  - 07/16/09: Minutes –Initial Review

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



## **GOG-0261**

Initial Review (IR): 2009

Documents Posted:

- Protocol
  - Protocol Version Date 08/20/09
  - Protocol Version Date 08/20/09 - Highlighted Changes
  - Protocol Version Date 07/01/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 08/20/09 [IR]
  
- CIRB Application
  - CIRB Application (Protocol Version Date 08/20/09)
  - CIRB Application (Protocol Version Date 07/01/09)
  
- Primary Reviews
  - 09/03/09: Primary Reviewer 1 Comments
  - 08/06/09: Primary Reviewer 1 Comments
  - 08/06/09: Primary Reviewer 2 Comments
  - 08/06/09: Primary Reviewer 3 Comments
  - 08/06/09: Primary Reviewer 4 Comments
  
- Correspondence
  - 09/08/09: GOG Activation Notice
  - 09/03/09: CIRB Final Approval Letter (Protocol Version Date 08/20/09)
  - 08/20/09: GOG Response to CIRB
  - 08/17/09: GOG Activation Notice
  - 08/13/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 07/01/09)
  
- Minutes
  - 08/06/09: Minutes - Initial Review
  
- Support Documents
  - Appendices (Protocol Version Date 07/01/09)

## **SWOG-S0819**

Initial Review (IR): 2009

Documents Posted:

- Minutes
  - 07/16/09: Minutes – Initial Review



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

## **Pediatric Studies**

Documents Posted:

- NONE

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

### **Adult Studies**

#### **ACOSOG-Z6051**

Amendment Review: Amendment #2 (Protocol Version Date 07/06/09)

Documents Posted:

- Amendments
  - 07/06/09: ACOSOG Change Memo (Protocol Version Date 07/06/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 07/06/09)
- Correspondence
  - 08/11/09: CIRB Amendment 2 Approval Letter (Protocol Version Date 07/06/09)
- Protocol
  - Protocol Version Date 07/06/09
  - Protocol Version Date 07/06/09 – Highlighted
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/06/09 [Am2]
- Primary Reviews
  - 08/06/09: Primary Reviewer 1 Comments

#### **CALGB-40503**

Amendment Review: Update #1 (Protocol Version Date 06/23/09)

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Update 1 Review



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

**CALGB-100104**

Amendment Review: Update #8 (Protocol Version Date 07/01/09)

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Update 8 Review

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

**CALGB-140503**

Amendment Review: Update #3 (Protocol Version Date 06/30/09)

Documents Posted:

- Minutes
  - 07/16/09: Minutes – Update 3 Review

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

**ECOG-E1A06**

Amendment Review: Addendum #2 (Protocol Version Date 07/22/09)

Documents Posted:

- Amendments
  - 07/22/09: Change Memo (Protocol Version Date 07/22/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 07/22/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 07/22/09)

Correspondence

- 08/25/09: CIRB Addendum 2 Approval Letter (Protocol Version Date 07/22/09)
- Protocol
  - Protocol Version Date 07/22/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/22/09 [Add2]



- Primary Reviews
  - 08/20/09: Primary Reviewer 1 Comments
- Minutes
  - 08/20/09: Minutes – Addendum 2 Review

#### **ECOG-E2805**

Amendment Review: Addendum #7 (Protocol Version Date 07/17/09)

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Addendum 7 Review

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

#### **ECOG-E5103**

Amendment Review: Addendum #4 (Protocol Version Date 07/16/09)

Documents Posted:

- Amendments
  - 07/16/09: Change Memo (Protocol Version Date 07/16/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 07/16/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 07/16/09)
- Correspondence
  - 08/25/09: CIRB Approval Letter Addendum 4 (Protocol Version Date 07/16/09)
- Support Documents
  - GWAS Supporting Documentation
  - Quality of Life Forms
- Protocol
  - Protocol Version Date 07/16/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/16/09 [Add4]
- Primary Reviews
  - 08/20/09: Primary Reviewer 1 Comments



- Minutes
  - 08/20/09: Minutes – Addendum 4 Review

#### **ECOG-E5202**

Amendment Review: Addendum #10 (Protocol Version Date 07/29/09)

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Addendum 10 Review

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

#### **ECOG-E5204**

Amendment Review: Addendum #4 (Protocol Version Date 07/17/09)

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Addendum 4 Review

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

#### **GOG-0212**

Amendment Review: Revision #7 (Protocol Version Date 06/12/09)

Documents Posted:

- Minutes
  - 07/16/09: Minutes – Revision 7 Review

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

#### **GOG-0219**

Amendment Review: **Study Suspended to Patient Entry effective September 1, 2009**

Documents Posted:

- Correspondence
  - 09/08/09: CIRB Tirapazamine Shortage and Temporary Closure to Accrual Letter
  - 08/17/09: GOG Suspension effective 09/01/09

#### **GOG-0249**

Amendment Review: Revision #3 (Protocol Version Date 08/04/09)



Documents Posted:

- Amendments
  - 08/04/09: Change Memo (Protocol Version Date 08/04/09)
- Correspondence
  - 08/12/09: CIRB Revision 3 Approval Letter (Protocol Version Date 08/04/09)
- Protocol
  - Protocol Version Date 08/04/09
  - Protocol Version Date 08/04/09 (Highlighted)
  - Appendix I - Clinical Staging - Carcinoma of the Corpus Uteri FIGO Classification
  - Appendix II - Specimen Procedures
  - Appendix III - Logistical Guidelines
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 08/04/09 [Rev3]

**NCCTG-N0147**

Amendment Review: CIRB Acknowledgement - Investigator Letter regarding the Role of Calcium & Magnesium (Ca/Mg)

Documents Posted

- Correspondence
  - 09/02/09: CIRB Acknowledgment of Investigator Letter regarding Ca/Mg
  - 08/20/09: NCCTG Investigator Letter regarding Ca/Mg
  - 07/17/07: NCCTG Investigator Notice regarding Ca/Mg

**NCCTG-N0723**

Amendment Review: Update#1 (Protocol Version Date 08/24/09)

Documents Posted:

- Amendments
  - Change Memo (Protocol Version Date 08/24/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 08/24/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 08/24/09)
- Correspondence



- 09/02/09: CIRB Update 1 Approval Letter (Protocol Version Date 08/24/09)
- Protocol
  - Protocol Version Date 08/24/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 08/24/09 [Up1]
  - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 08/24/09 [up1]

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

Amendment Review: Amendment #3 (Protocol Version Date 01/23/09)

Documents Posted:

- Amendments
  - 01/23/09: Change Memo (Protocol Version Date 01/23/09)
- CIRB Application
  - CIRB Application Protocol Version Date 01/23/09
  - Summary of CIRB Application Revisions (Protocol Version Date 01/23/09)
- Correspondence
  - 02/10/09: CIRB Amendment 3 Approval (Protocol Version 01/23/09)
  - 01/28/09: Cover Memo
- Protocol
  - Protocol Version Date 01/23/09
- Informed Consent
  - Informed Consent Document for Protocol Version Date 01/23/09 (Am3) Randomized Study

#### **RTOG-0521**

Amendment Review: Update 08/20/09 (Protocol Version Date 07/28/09)

Documents Posted:

- Amendments
  - 08/20/09 Change Memo (Protocol Version Date 07/28/09)
- Correspondence
  - 09/02/09: CIRB 08/20/09 Update Approval Letter (Protocol Version Date 07/28/09)



- Protocol
  - Protocol Version Date 07/28/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/28/09 (Up082009)
  - CIRB's Informed Consent Document for Protocol Version Date 07/28/09 (Up082009): Tissue)

#### **SWOG-S0106**

Amendment Review: CIRB Acknowledgement - Study Closure & Dear Participant and Dear Doctor Letters

Documents Posted:

- Correspondence
  - 08/31/09: CIRB Acknowledgement of Receipt for Study Closure and Participant and Doctor Letters
  - 08/20/09: SWOG Notification of Study Closure -- Effective August 20, 2009
- Support Documents
  - Dear Participant Letter
  - Dear Doctor Letter

#### **SWOG-S0307**

Amendment Review: Clodronate Shortage 3

Documents Posted:

- Correspondence
  - 09/09/09: CIRB Acknowledgement of Clodronate Shortage Memo
  - 08/20/09: SWOG Clodronate Drug Shortage Memo

Amendment Review: Revision #5 (Protocol Version Date 07/13/09)

Documents Posted:

- Amendments
  - 07/13/09: Change Memo (Protocol Version Date 07/13/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 07/13/09)
  - Summary CIRB Application Revisions (Protocol Version Date 07/13/09)
- Correspondence



- 08/25/09: CIRB Revision 5 Approval Letter (Protocol Version Date 07/13/09)
- Protocol
  - Protocol Version Date 07/13/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/13/09 [Rev5]
  - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 07/13/09 [Rev5]
- Primary Reviews
  - 08/20/09: Primary Reviewer 1 Comments
- Minutes
  - 08/20/09: Minutes - Revision 5 Review

Amendment Review: CIRB Approval with Query - Clodronate Shortage

Documents Posted:

- Correspondence
  - 09/09/09: Acknowledgement of the Group Response to the CIRB Query
  - 08/25/09: Group Response to CIRB Query Regarding Clodronate Shortage

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

#### **SWOG-S0502**

Amendment Review: Revision #3 (Protocol Version Date 09/01/09)

Documents Posted:

- Amendments
  - 09/01/09: Change Memo (Protocol Version Date 09/01/09)
- CIRB Application
  - CIRB Application (Protocol Version Date 09/01/09)
  - Summary of CIRB Application Revisions (Protocol Version Date 09/01/09)
- Correspondence
  - 09/08/09: CIRB Revision #3 Approval Letter (Protocol Version Date 09/01/09)



- Support Documents
  - OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol
  - Protocol Version Date 09/01/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 09/01/09 [Rev3]
  - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 09/01/09 [Rev3]

Amendment Review: CIRB Acknowledgement - Permanent Closure effective October 1, 2009

- Correspondence
  - 09/14/09: CIRB Acknowledgement of Closure of Accrual
  - 09/09/09: SWOG Closure Memo

## **Pediatric Studies**

### **COG-AALL03N1**

Amendment Review (AR): Amendment #4 (Protocol Version Date 08/14/2009)

Documents Posted:

- CIRB Application
  - CIRB Application (Protocol Version Date 08/14/09)
- Correspondence
  - 09/07/09: COG-AALL03N1 Amendment #4 Activation Memo
  - 09/04/09: CIRB Acknowledgement of Activation of Amendment #4 (Protocol Version Date 08/14/09)
  - 09/01/09: CIRB Approval of COG-AALL03N1 Amendment #4 (Protocol Version Date 08/14/09)
  - 08/14/09: COG Change Memo (Protocol Version Date 08/14/09)
- Protocol
  - Protocol Version Date 08/14/09
  - Protocol Version Date 08/14/09 - Highlighted Changes
- Informed Consent
  - Informed Consent Document for Protocol Version Date 08/14/09

### **COG-ADVL0525**



**\*\*Partial Closure for Medulloblastoma and Non-Brainstem High Grade Glioma Strata - Effective July 23, 2009\*\***

Amendment Review (AR): [Acknowledgement of COG ADVL0525 Partial Closure for Medulloblastoma and Non-Brainstem High Grade Glioma Disease Strata \(07/23/09\)](#)

Documents Posted:

- Correspondence
  - 08/26/09: CIRB Acknowledgement: ADVL0525 Medulloblastoma and Non-Brainstem High Grade Glioma Disease Strata Closure
  - 07/23/09: COG Notice: ADVL0525 Medulloblastoma and Non-Brainstem High Grade Glioma Disease Strata Closure

**COG-ADVL0821**

**\*\*Partial Closure of the Neuroblastoma (Measurable Disease) Stratum by COG of ADVL0821 -- Effective September 3, 2009\*\***

Amendment Review (AR): [Partial Closure for ADVL0821 - Neuroblastoma \(Measurable Disease\) Stratum -- \(09/03/2009\)](#)

Documents Posted:

- Correspondence
  - 09/04/09: CIRB Acknowledgement - ADVL0821 Partial Closure for Neuroblastoma (Measurable Disease) Stratum
  - 09/03/09: COG Notice - ADVL0821 Partial Closure for Neuroblastoma (Measurable Disease) Stratum

Amendment Review (AR): Amendment #2 Protocol Version Date 06/02/09

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Amendment Review

**[Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.](#)**

**COG-AOST06P1**

Amendment Review (AR): Amendment #3 (Protocol Version Date 08/27/2009)

Documents Posted:

- CIRB Application
  - CIRB Application (Protocol Version Date 08/27/09)
- Correspondence
  - 09/07/09: COG-AOST06P1 Amendment #3 Activation Memo
  - 09/04/09: CIRB Acknowledgement of COG AOST06P1 Amendment #3 (Protocol Version Date 08/27/09)



- 09/01/09: CIRB Approval of COG-AOST06P1 Amendment #3 (Protocol Version Date 08/27/09)
- 08/27/09: COG Change Memo (Protocol Version Date 08/27/09)
  
- Protocol
  - Protocol Version Date 08/27/09
  - Protocol Version Date 08/27/09 - Highlighted Changes
  
- Informed Consent
  - Informed Consent Document for Protocol Version Date 08/27/09

### **COG-AREN0532**

Amendment Review (AR): Amendment #3 (Protocol Version Date 06/05/09)

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Amendment Review

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

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

#### **Adult Studies**

### **CALGB-10201**

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 05/02/07)
  
- Correspondence
  - 09/10/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/02/07)
  - 07/06/09: Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 05/02/07
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 05/02/07 [CR09]



- Support Documents
  - June 2007 - Study Summary

#### **ECOG-E2499**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Continuing Review

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

#### **ECOG-E3201**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 06/26/08)
- Correspondence
  - 08/31/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/08)
  - 07/07/09: Continuing Review Reminder Notice
- Protocol
  - Protocol Version Date 06/26/08
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 06/26/08 [CR09]
- Support Documents
  - November 2005 - Study

#### **ECOG-E5202**

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 07/29/09)
- Correspondence



- 09/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/29/09)
- 07/07/09: Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 07/29/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 07/29/09 [CR09]
  
- Support Documents
  - June 2009 - Study Summary
  - April 2009 - DMC Recommendations
  
- Primary Reviews
  - 09/03/09: Primary Reviewer 1 Comments

#### **GOG-0249**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/16/09: Minutes – Continuing Review

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

#### **NSABP-B-33**

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 03/26/07)
  
- Correspondence
  - 09/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
  - 08/14/09: Cover Memo
  - 07/06/09: CIRB Continuing Review Reminder
  
- Protocol
  - Protocol Version Date 03/26/07
  
- Informed Consent



- CIRB's Informed Consent Document for Protocol Version Date 03/26/07: [CR09]
- CIRB's Informed Consent Document for Protocol Version Date 03/26/07: Add 1 [CR09]
- CIRB's Informed Consent Document for Protocol Version Date 03/26/07: Add 2 [CR09]
- CIRB's Informed Consent Document for Protocol Version Date 03/26/07: Sub Study [CR09]
  
- Support Documents
  - Study Summary
  
- Primary Reviews
  - 09/03/09: Primary Reviewer 1 Comments

### **NSABP-B-39/RTOG-0413**

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 03/13/07)
  
- Correspondence
  - 09/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/13/07)
  - 08/20/09: Cover Memo
  - 07/06/09: CIRB Continuing Review Reminder
  
- Protocol
  - Protocol Version Date 03/13/07
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 03/13/07 [CR09]
  - CIRB's Informed Consent Document (Notes for Local Institutions) for Protocol Version Date 03/13/07 [CR09]
  
- Primary Reviews
  - 09/03/09: Primary Reviewer 1 Comments
  
- Support Documents
  - 04/17/09: DMC Minutes
  - 10/17/08: DMC Minutes
  - Study Summary
  - ASTRO Abstract - APBI (Benjamin Smith et.al)



- Elsevier Abstract - APBI (Antonucci et.al)
- Elsevier Abstract - APBI (Chen et.al)
- Elsevier Abstract - APBI (Hepel et.al)
- Elsevier Abstract - APBI (Jagsi et.al)
- Elsevier Abstract - APBI (Prosnitz et.al)

#### **NSABP-B-40**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/16/09: Minutes – Continuing Review

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

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

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 03/25/09)
- Correspondence
  - 07/06/09: Continuing Review Reminder Notice
  - 08/19/09: NSABP Cover memo
  - 09/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/25/09)
- Protocol
  - Protocol Version Date 03/25/09
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 03/25/09 [CR09]
  - CIRB's Informed Consent Document for Protocol Version Date 03/25/09: Addendum 1
  - CIRB's Informed Consent Document for Protocol Version Date 03/25/09: Addendum 2
  - CIRB's Informed Consent Document for Protocol Version Date 03/25/09: Tissue
  - CIRB's Informed Consent Document (Notes for Local Institutions) for Protocol Version Date 03/25/09 [CR09]
- Primary Reviews



- 09/03/09: Primary Reviewer 1 Comments
- Support Documents
  - NSABP Study Summary (Protocol Version Date 03/25/09)
  - 04/17/09: DMC Meeting Minutes
  - 10/17/08: DMC Meeting Minutes
  - 04/25/08: DMC Meeting Minutes

#### **RTOG-0521**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Continuing Review

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

#### **RTOG-0522**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Continuing Review

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

#### **SWOG-0226**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Continuing Review

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

#### **SWOG-0500**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Minutes
  - 08/06/09: Minutes – Continuing Review



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

#### **SWOG-S0518**

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 02/20/09)
  
- Correspondence
  - 09/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/20/09)
  - 07/06/09: Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 02/20/09
  
- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 02/20/09 (CR09)
  
- Primary Reviews
  - 09/03/09: Primary Reviewer 1 Comments
  
- Support Documents
  - April 2009 - Study Summary
  - 04/07/09: DSMC Minutes

#### **SWOG-S0777**

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 07/15/09)
  
- Correspondence
  - 09/08/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/08/09)
  - 07/07/09: Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 05/08/09



- Informed Consent
  - CIRB's Informed Consent Document for Protocol Version Date 05/08/09 [CR09]
- Primary Reviews
  - 09/03/09: Primary Reviewer 1 Comments
- Support Documents
  - 04/07/09: Final minutes of SWOG Data and Safety Monitoring Committee
  - October-November 2008: Study Summary

## **Pediatric Studies**

### **COG-AALL0622**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

### **COG-AALL07P4**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

### **COG-AALL08P1**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

### **COG-AAML05P1**



Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**COG-AAML08B1**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 01/22/09)
  
- Correspondence
  - 09/01/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/22/09)
  - 08/05/09: CIRB Continuing Review Reminder Notice
  
- Protocol
  - Protocol Version Date 01/22/09
  
- Informed Consent
  - Informed Consent Document for Protocol Version Date 01/22/09

**COG-ACNS0332**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**COG-ADVL0221**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review



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

**COG-AEWS07B1**

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Continuing Review Forms
  - CIRB Continuing Review Application (Protocol Version Date 02/10/09)
  
- Correspondence
  - 09/01/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/01/09)
  - 08/05/09: CIRB Continuing Review Reminder Notice
  
- Informed Consent
  - Informed Consent Document for Protocol Version Date 02/10/09 - At Initial Diagnosis
  - Informed Consent Document for Protocol Version Date 02/10/09 - Recurrence
  
- Primary Reviews
  - Protocol Version Date 02/10/09

**COG-ANBL0531**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**COG-ANBL0532**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**COG-ARET0231**



Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**COG-ARET0321**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**COG-ASCT0431**

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Minutes
  - 07/09/09: Minutes - Continuing Review

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

**Serious Adverse Events Posted**

**Adult Studies**

**Study Number**

**CALGB 100104**

**SAEs posted:**

**1277486**

**163-C5013-09030612 FU1**

**1673759**

**1673759 FU1**

**CALGB 10501**



**SAEs posted:**  
556768 FU

**CALGB 10603**

**SAEs posted:**  
PHHO2008GB12867  
PHHO2008US06834 FU 1

**CALGB 30607**

**SAEs posted:**  
1140081  
1491694  
1704399  
2008013916

**CALGB 40101**

**SAEs posted:**  
1353951

**CALGB 40302**

**SAEs posted:**  
B0551062A  
B0567619A FU1  
Z0000661A FU

**CALGB 40601**

**SAEs posted:**  
Z0000661A FU

**CALGB 50303**

**SAEs posted:**  
556768 FU

**ECOG E1105**

**SAEs posted:**  
1133874 FU1  
1158823 FU1  
1192440  
1201753 FU1



1202538  
1232396  
1257729  
1257729 FU1  
1314985 FU1  
1329128 FU1  
1333814  
1353951  
1360351 FU1  
1390754  
1390754 FU1  
1392926  
1687519  
1718620 and 1718620 FU1 (corrected report)  
1809441 FU1  
1833568  
1839475  
1839475 FU1  
1881593 FU1  
1950915  
1968432 FU1  
1987521 FU1  
1994045 FU1

**ECOG E1A05**

**SAEs posted:**

1073953  
1203233  
1277486  
163-C5013-09030612 FU1  
1673759  
1673759 FU1

**ECOG E1A06**

**SAEs posted:**

1203233  
1277486  
163-C5013-09030612 FU1  
1673759  
1673759 FU1

**ECOG E2603**

**SAEs posted:**



1704399

**ECOG E2805**

**SAEs posted:**

1633079 FU1

1704399

**ECOG E2905**

**SAEs posted:**

163-C5013-09030612 FU1

**ECOG E4402**

**SAEs posted:**

556768 FU1

**ECOG E4A03**

**SAEs posted:**

1203233

1277486

1358268 FU1

1628411

163-C5013-09030612 FU1

1673759

1673759 FU1

**NCCTG N0723**

**SAEs posted:**

1859262

1859262 FU1

**NSABP C-08**

**SAEs posted:**

1158823 FU1

1192440

1201753 FU1

1202538

1232396

1293580

1329128

1333814



1360351 FU1  
1390754  
1391765  
1392926  
1419144  
1718620 FU1  
1833568  
1836781  
1950915  
1968432 Fu1  
273064 FU2  
273064 FU3

**SWOG S0777**

**SAEs posted:**

1073953  
1203233  
1277486  
1628411  
163-C5013-09030612 FU1  
1673759  
1673759 FU1

**Pediatric Studies**

**Study Number**

**COG ADVL0525**

**SAEs posted:**

BE200903001203  
BE200906001278  
BE200906004270  
BE200906004270 FU1  
BE200907000120  
BE200907000120 FU1  
BE200907001461  
BE200907003374  
BR200807000959 FU1  
DE200902003576  
DE200906006252  
EG200907001331  
FR200901005537 FU1  
FR200903006927



FR200906000735  
FR200906005621  
FR200906006042  
FR200907002965  
GR200907003375  
HU200904001274  
IN200906005974  
IN200906005974 FU1  
IN200907002961  
IN200907002961 FU1  
IT200906005833  
NL200907000674  
PL200906004558  
US200906006757  
US200907000920  
US200907001688  
US200907003699

**COG AEWS0521**

**SAEs posted:**

1391765  
1392926  
1419144  
1687519  
1718620  
1809441  
1809441 FU1  
1833568  
1836781  
1839475  
1839475 FU1  
1950915  
1987521 FU1

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**Corrections to Previous Postings**

**Adult Studies**

**Study Number**

Documents Posted:  
Correction:



- NONE

## **Pediatric Studies**

<b><u>Study Number</u></b>
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Documents Posted:

Correction:

- 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.