



NCI Central IRB Website Postings Summary

February 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 1st and 15th 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 or call the CIRB HelpDesk toll-free at 888-657-3711.

CIRB Notices

- NONE
-

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-ARST08P1

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 11/25/09
 - Protocol Version Date 11/25/09 - Highlighted Changes
 - Protocol Version Date 10/14/09

- Informed Consent
 - Informed Consent Document for Protocol Version Date 11/25/09: Pilot 1
 - Informed Consent Document for Protocol Version Date 11/25/09: Pilot 2
 - Informed Consent Document for Protocol Version Date 11/25/09: Pilot 3

- CIRB Application
 - CIRB Application (Protocol Version Date 11/25/09)
 - CIRB Application (Protocol Version Date 10/14/09)

- Primary Reviews
 - 11/12/09: Primary Reviewer 1 Comments
 - 11/12/09: Primary Reviewer 2 Comments
 - 11/12/09: Primary Reviewer 3 Comments
 - 11/12/09: Pharmacist Reviewer Comments
 - 11/12/09: Statistician Reviewer Comments

- Correspondence
 - 01/19/10: COG Activation of ARST08P1 Memo
 - 01/18/10: CIRB Acknowledgement of COG-ARST08P1 Activation Memo
 - 12/08/09: CIRB Final Approval Letter of COG-ARST08P1 (Protocol Version Date 11/25/09)
 - 11/25/09: COG Response to CIRB Approval Pending Modification Letter of Initial Review of ARST08P1 (Protocol Version Date 11/25/09)
 - 11/20/09: CIRB Approval Pending Modification Letter of Initial Review of ARST08P1 (Protocol Version Date 10/14/09)

- Minutes
 - 11/12/09: Minutes - Initial Review



Posted Documents Related to Amendment Reviews:

Adult Studies

ACOSOG-Z4032

Closed to Accrual - effective January 22, 2010

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

Documents Posted:

- Correspondence
 - 01/25/10: CIRB Acknowledgement of ACOSOG Z4032 Closure to Accrual
 - 01/07/10: ACOSOG Closure to Accrual Memo

CALGB-40502

Amendment Review (AR): Update #1 (Protocol Version Date 12/16/09)

Documents Posted:

- Amendments
 - CALGB Change Memo (Protocol Version Date 12/16/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 12/16/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 12/16/09)
- Correspondence
 - 01/08/10: CIRB Approval Letter Update 1 (Protocol Version Date 12/16/09)
- Support Documents
 - CALGB Physical Activity Questionnaire (Form C-1957)
- Protocol
 - Protocol Version Date 12/16/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 12/16/09 [Up1]
- Primary Reviews
 - 01/07/10: Primary Reviewer 1 Comments - Update 1

CALGB-100104

Amendment Review (AR): Update #9 (Protocol Version Date 12/08/09)

Documents Posted:

- Amendments
 - CALGB Update 9 Change Memo (Protocol Version Date 12/08/09)



- CIRB Application
 - CIRB Application (Protocol Version Date 12/08/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 12/08/09)
- Correspondence
 - 12/16/09 CIRB Approval Letter Update 9 (Protocol Version Date 12/08/09)
- Support Documents
 - OHRP: IRB Review of Protocol & Informed Consent Changes
- Protocol
 - Protocol Version Date 12/08/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 12/08/09 [up9]

ECOG-E3F05

Amendment Review (AR): Update #2 (Protocol Version Date 01/06/10)

Documents Posted:

- Amendments
 - January 2010 - Change Memo (Protocol Version Date 01/06/10)
- CIRB Application
 - CIRB Application (Protocol Version Date 01/06/10)
 - Summary of CIRB Application Revisions (Protocol Version Date 01/06/10)
- Correspondence
 - 01/13/10: CIRB Approval Letter Update 2 (Protocol Version Date 01/06/10)
- Protocol
 - Protocol Version Date 01/06/10
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 01/06/10 [Up2]

ECOG-E3805

Amendment Review (AR): Addendum #4 (Protocol Version Date 12/31/09)

Documents Posted:

- Amendments
 - ECOG Addendum 4 Change Memo (Protocol Version Date 12/31/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 12/31/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 12/31/09)



- Correspondence
 - 01/08/10: CIRB Approval Letter Addendum 4 (Protocol Version Date 12/31/09)
- Protocol
 - Protocol Version Date 12/31/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 12/31/09 [Add4]

ECOG-E5204

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/14/10: CIRB Acknowledgement of ECOG E5204 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

GOG-0213

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of GOG 0213 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

GOG-0218

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of GOG 0218 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

GOG-0240

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of GOG 0240 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

GOG-0250

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)



Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of GOG 0250 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

GOG-0252

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of GOG 0252 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

NCCTG-N0147

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

Documents Posted:

- Minutes
 - 12/17/09: Minutes – Unanticipated Problem Determination (Closure)

[Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.](#)

NSABP-B-35

Amendment Review (AR): [CIRB Acknowledgement - Updated ARIMIDEXTM \(anastrozole, ZD1033\) Investigator's Brochure Edition 12 dated 17 December 2007](#)

Documents Posted:

- Correspondence
 - 01/20/10: CIRB Acknowledgement of NSABP B-35 Updated ARIMIDEXTM (anastrozole, ZD1033) Investigator's Brochure Edition 12 dated 17 December 2007

NSABP-B-38

Amendment Review (AR): [CIRB Acknowledgement - Retired Gemcitabine Investigator's Brochure dated October 26, 2009](#)

Documents Posted:

- Correspondence
 - 01/21/10: CIRB Acknowledgement of NSABP B-38 Retired Gemcitabine Investigator's Brochure dated October 26, 2009



NSABP-B-40

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/20/10: CIRB Acknowledgement of NSABP B-40 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

Amendment Review (AR): [CIRB Acknowledgement - Updated Xeloda® \(capecitabine\) Investigator's Brochure Version 11 dated August 2009](#)

Documents Posted:

- Correspondence
 - 01/20/10: CIRB Acknowledgement of NSABP B-40 Updated Xeloda® (capecitabine) Investigator's Brochure Version 11 dated August 2009

Amendment Review (AR): [CIRB Acknowledgement - Retired Gemcitabine Investigator's Brochure dated October 26, 2009](#)

Documents Posted:

- Correspondence
 - 01/21/10: CIRB Acknowledgement of NSABP B-40 Retired Gemcitabine Investigator's Brochure dated October 26, 2009

NSABP-R-04

Amendment Review (AR): [CIRB Acknowledgement - Updated Xeloda® \(capecitabine\) Investigator's Brochure Version 11 dated August 2009](#)

Documents Posted:

- Correspondence
 - 01/20/10: CIRB Acknowledgement of NSABP R-04 Updated Xeloda® (capecitabine) Investigator's Brochure Version 11 dated August 2009

RTOG-0825

Amendment Review (AR): [CIRB Acknowledgement - Updated Avastin® \(bevacizumab\) Investigator's Brochure Version 17 dated November 2009](#)

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of RTOG 0825 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009



SWOG-S0307

Amendment Review (AR): ****Permanent Closure – effective February 1, 2010****

Documents Pending

SWOG-S0502

Amendment Review (AR): **CIRB Acknowledgement - Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009**

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of SWOG S0502 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

SWOG-S0518

Amendment Review (AR): **CIRB Acknowledgement - Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009**

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of SWOG S0518 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

****Temporary Closure to Step 2 (SPECT Substudy) - effective January 22, 2010****

Amendment Review (AR): **CIRB Acknowledgement - Temporary Closure to Step 2 (SPECT Substudy)**

Documents Posted:

- Correspondence
 - 01/28/10: CIRB Acknowledgement of SWOG S0518 Temporary Closure to Step 2 (SPECT Substudy)
 - 01/22/10: SWOG Temporary Closure to Step 2 (SPECT Substudy) Memo

SWOG-S0600

Amendment Review (AR): **CIRB Acknowledgement - Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009**

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of SWOG S0600 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009



SWOG-S0819

Amendment Review (AR): **CIRB Acknowledgement - Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009**

Documents Posted:

- Correspondence
 - 01/20/10: CIRB Acknowledgement of SWOG S0819 Updated Avastin® (bevacizumab) Investigator's Brochure Version 17 dated November 2009

Pediatric Studies

COG-AALL03N1

Amendment Review (AR): Amendment #5 (Protocol Version Date 12/10/09)

Documents Posted:

- Amendments
 - 12/10/09: COG Change Memo (Protocol Version Date 12/10/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 12/10/09)
- Correspondence
 - 01/25/10: COG-AALL03N1 Amendment #5 Activation Memo
 - 01/22/10: CIRB Acknowledgement of Activation of Amendment #5 (Protocol Version Date 12/10/09)
 - 01/13/10: CIRB Approval of COG-AALL03N1 Activation Amendment #5 (Protocol Version Date 12/10/09)
- Protocol
 - Protocol Version Date 12/10/09
 - Protocol Version Date 12/10/09 - Highlighted Changes
- Informed Consent
 - Informed Consent Document for Protocol Version Date 12/10/09 [Per Amd. 5]

COG-AALL0622

Amendment Review (AR): Activation Amendment #3 (Protocol Version Date 12/04/2009)

Documents Posted:

- Amendments
 - 12/04/09: COG Change Memo (Protocol Version Date 12/04/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 12/04/09)



- Correspondence
 - 01/18/10: CIRB Acknowledgement of COG AALL0622 Amendment #3 Activation (Protocol Version Date 12/04/09)
 - 01/18/10: COG-AALL0622 Amendment #3 Activation Memo
 - 01/11/10: CIRB Approval of COG-AALL0622 Activation Amendment #3 (Protocol Version Date 12/04/09)
- Protocol
 - Protocol Version Date 12/04/09
 - Protocol Version Date 12/04/09 - Highlighted Changes
- Informed Consent
 - Informed Consent Document for Protocol Version Date 12/04/09: [Per Amd. 3]
 - Informed Consent Document for Protocol Version Date 12/04/09: [Per Amd. 3] - DFCI

Amendment Review (AR): [CIRB Acknowledgement of COG-AALL0622 Patient/Family Memo \(Dated 12/15/09\) regarding Steroid Use During Maintenance Therapy](#)

Documents Posted:

- Correspondence
 - 01/25/10: CIRB Acknowledgement of COG-AALL0622 Patient/Family Memo
 - 12/15/09: COG-AALL0622 Patient/Family Memo re Steroid Use During Maintenance Therapy

COG-ACCL0431

****Temporary Closure to Accrual by COG – Effective January 22, 2010****

Amendment Review (AR): [CIRB Acknowledgement of Temporary Closure of COG-ACCL0431 \(01/22/10\)](#)

Documents Posted:

- Correspondence
 - 01/27/10: CIRB Acknowledgement of Temporary Closure of COG-ACCL0431
 - 01/22/10: COG Memo - Temporary Closure of Study ACCL0431

COG-ACNS0333

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
 - 12/08/09: COG Participant Notification Letter - ACNS0333 Temporary Suspension (Revised by COG 01/14/10)

[Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.](#)



COG-AEWS07P1

****Closed to Accrual by COG - Effective January 15, 2010****

Amendment Review (AR): **CIRB Acknowledgement of COG-AEWS07P1 Study Closure (01/15/10)**

Documents Posted:

- Correspondence
 - 01/19/10: CIRB Acknowledgement of COG-AEWS07P1 Closure to Accrual Memo
 - 01/15/10: COG Memo - Closure of AEWS07P1 - Effective January 15, 2010
- Informed Consent
 - Informed Consent Document for Protocol Version Date 10/12/07: [As of Study Closure 01/15/10]

COG-ANBL0931

Amendment Review (AR): **CIRB Acknowledgement - Notification of Aldesleukin Compounding Instructions**

Documents Posted:

- Correspondence
 - 01/18/10: CIRB Acknowledgement of Aldesleukin Compounding Instructions
 - 01/12/10: COG Memo - Aldesleukin Compounding Instructions

COG-AREN0321

****Temporary Suspension of Accrual onto the Window Therapy Arm - Effective January 20, 2010****

Amendment Review (AR): **CIRB Acknowledgement of COG-AREN0321 Temporary Suspension of Accrual onto the Window Therapy Arm (01/20/10)**

Documents Posted:

- Correspondence
 - 01/25/10: CIRB Acknowledgement of AREN0321 Temporary Suspension of the Window Therapy Arm Memo
 - 01/20/10: COG Participant Notification - AREN0321 Temporary Suspension of the Window Therapy Arm



Posted Documents Related to Continuing Reviews:

Adult Studies

CALGB-90104

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 03/26/07)
- Correspondence
 - 01/14/10: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
- Protocol
 - Protocol Version Date 03/26/07
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/26/07 [CR10]
- Support Documents
 - DSMB Statements - June 2005
 - Study Summary - June 2006

CALGB-90203

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: 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:

- Minutes
 - 12/17/09: 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-N06C6

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 07/01/09)

- Correspondence
 - 01/27/10: CIRB Continuing Review Approval Letter (Protocol Version Date 07/01/09)
 - 12/04/09: Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 07/01/09

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/01/09 [CR10]
 - CIRB's Informed Consent Document (Instructions for Local institutions) for Protocol Version Date 07/01/09 [CR10]

- Support Documents
 - September 2009 - DMC AE Report

NCCTG-N0723

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: Minutes - Continuing Review

[Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.](#)

NSABP-C-08

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 10/25/07)

- Correspondence
 - 01/21/10: CIRB Continuing Review Approval Letter (Protocol Version Date 10/25/07)
 - 01/21/10: NSABP Cover Memo
 - 12/04/09: Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 10/25/07



- Informed Consent
 - CIRB's Informed Consent Document-Main for Protocol Version Date 10/25/07 [CR10]
 - CIRB's Informed Consent Document- Addendum 1 for Protocol Version Date 10/25/07 [CR10]
 - CIRB's Informed Consent Document- Addendum 2 for Protocol Version Date 10/25/07 [CR10]
- Support Documents
 - Study Summary

SWOG-9007

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: 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-S0309

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: 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-S0337

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: 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-S9910

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: 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-S9925

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/17/09: Minutes - Continuing Review

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

Pediatric Studies

COG-AALL0331

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-AALL03N1

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 08/14/09)
- Correspondence
 - 01/13/10: CIRB Continuing Review Approval Letter (Protocol Version Date 08/14/09)
 - 12/07/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 08/14/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/14/09 [Per Jan. 10 CR]
- Support Documents
 - 09/08/09: Study Progress Report - Fall 2009



COG-AALL0433

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 05/07/09)
- Correspondence
 - 01/22/10: CIRB Continuing Review Approval Letter (Protocol Version Date 05/07/09)
 - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 05/07/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 05/07/09 [Per Jan. 10 CR]
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - 11/01/08: Study Progress Report - Spring 2009

COG-AALL0434

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 10/31/08)
 - CIRB Continuing Review Application - Revised (Protocol Version Date 10/31/08)
- Correspondence
 - 01/18/10 CIRB Continuing Review Approval Letter (Protocol Version Date 10/31/08)
 - 12/23/09: COG Response to CIRB Table of the Continuing Review of COG-AALL0434 Letter (Protocol Version Date 10/31/08)
 - 12/22/09: CIRB Table of Continuing Review of COG- AALL0434 Letter (Protocol Version Date 10/31/08)
 - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 10/31/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 10/31/08: [Per Dec. 09 CR] Part II - Low Risk
 - Informed Consent Document for Protocol Version Date 10/31/08: [Per Dec. 09 CR] Part II - Intermediate Risk



- Informed Consent Document for Protocol Version Date 10/31/08: [Per Dec. 09 CR] Part II - High Risk
- Informed Consent Document for Protocol Version Date 10/31/08: [Per Dec. 09 CR] Part I - Induction Therapy
- Informed Consent Document for Protocol Version Date 10/31/08: [Per Dec. 09 CR] Part II - Induction Failure

- Primary Reviews
 - 12/10/09: Primary Reviewer 1 Comments

- Minutes
 - 12/10/09: Minutes - Continuing Review

- 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:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-AAML0531

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-ABTR04B1

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 10/12/09)

- Correspondence
 - 01/14/10: CIRB Continuing Review Approval Letter (Protocol Version Date 10/12/09)
 - 11/04/09: CIRB Continuing Review Reminder Notice



- Protocol
 - Protocol Version Date 10/12/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 10/12/09 [Per Jan. 10 CR]
- Support Documents
 - 05/01/09: Study Progress Report - Fall 2009

COG-ACCRN07

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 08/06/08)
- Correspondence
 - 01/13/10: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/08)
 - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 08/06/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/06/08 [Per Jan. 10 CR]: Parental Consent
 - Informed Consent Document for Protocol Version Date 08/06/08 [Per Jan. 10 CR]: Patient Consent
 - Assent Form Document for Protocol Version Date 08/06/08 [Per Jan. 10 CR]
- Support Documents
 - Information Sheet for ACCRN07 (Protocol Version Date 08/06/08)
 - Permission Forms for ACCRN07 (Protocol Version Date 08/06/08)

COG-ACNS0221

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 11/15/05)
- Correspondence
 - 01/18/10: CIRB Continuing Review Approval Letter (Protocol Version Date 11/15/05)
 - 11/04/09: CIRB Continuing Review Reminder Notice



- Protocol
 - Protocol Version Date 11/15/05
- Informed Consent
 - Informed Consent Document for Protocol Version Date 11/15/05: [Per Jan. 10 CR]
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - 11/01/08: Study Progress Report - Spring 2009

COG-ACNS0333

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 11/07/08)
- Correspondence
 - 01/14/10: CIRB Continuing Review Approval Letter (Protocol Version Date 11/07/08)
 - 12/30/09: COG Response to Approval Pending Modification of Continuing Review Letter (Protocol Version Date 11/07/08)
 - 12/22/09: CIRB Approval Pending Modification of Continuing Review Letter (Protocol Version Date 11/07/08)
 - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 11/07/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 11/07/08 [Per Dec. 09 CR]
- Primary Reviews
 - 12/10/09: Primary Reviewer 1 Comments
- Minutes
 - 12/10/09: Minutes - Continuing Review
- Support Documents
 - 10/12/09: DSMC Report - Fall 2009
 - 09/08/09: Study Progress Report - Fall 2009

COG-ADVL0524

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 10/01/07)



- Correspondence
 - 01/20/10: CIRB Continuing Review Approval Letter (Protocol Version Date 10/01/07)
 - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 10/01/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 10/01/07 [Per Jan. 10 CR]
- Support Documents
 - 05/01/09: Study Progress Report - Fall 2009
 - 03/24/09: DSMC Report - Spring 2009

COG-ADVL0525

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-AEWS07P1

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-AHOD03P1

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/30/09)
- Correspondence
 - 01/22/10: 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 Jan. 10 CR]
- Support Documents
 - 10/12/09: DSMC Report - Fall 2009
 - 05/01/09: Study Progress Report - Fall 2009

COG-AHOD0431

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 05/11/07)
- Correspondence
 - 01/22/10: CIRB Continuing Review Approval Letter (Protocol Version Date 05/11/07)
 - 11/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 05/11/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 05/11/07 [Per Jan. 10 CR]: Initial Treatment
 - Informed Consent Document for Protocol Version Date 05/11/07 [Per Jan. 10 CR]: Relapse Treatment
- Support Documents
 - 10/12/09: DSMC Report - Fall 2009
 - 09/08/09: Study Progress Report - Fall 2009

COG-ANBL00P3

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/25/09)
- Correspondence
 - 01/18/10 CIRB Continuing Review Approval Letter (Protocol Version Date 09/25/09)
 - 12/07/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 09/25/09



- Informed Consent
 - Informed Consent Document for Protocol Version Date 09/25/09: [Per Jan. 10 CR] - Low Risk
 - Informed Consent Document for Protocol Version Date 09/25/09: [Per Jan. 10 CR] - Intermediate/High Risk
- Support Documents
 - 10/12/09: DSMC Report - Fall 2009
 - 09/08/09: Study Progress Report - Fall 2009

COG-AOST0331

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 08/03/09)
- Correspondence
 - 01/14/10: CIRB Continuing Review Approval Letter (Protocol Version Date 08/03/09)
 - 12/23/09: COG Response to Approval Pending Modification of Continuing Review Letter (Protocol Version Date 08/03/09)
 - 12/22/09: CIRB Approval Pending Modification of Continuing Review 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] - Part 1: Induction Therapy
 - Informed Consent Document for Protocol Version Date 08/03/09 [Per Dec. 09 CR] - Part 2: Good Response
 - Informed Consent Document for Protocol Version Date 08/03/09 [Per Dec. 09 CR] - Part 2: Poor Response
- Primary Reviews
 - 12/10/09: Primary Reviewer 1 Comments
- Minutes
 - 12/10/09: Minutes - Continuing Review
- Support Documents
 - 10/23/09: DSMC Report - Fall 2009
 - 05/01/09: Study Progress Report - Fall 2009



COG-ARAR0331

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/14/09)

- Correspondence
 - 01/18/10: CIRB Continuing Review Approval Letter (Protocol Version Date 04/14/09)
 - 11/04/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 04/14/09

- Informed Consent
 - Informed Consent Document for Protocol Version Date 04/14/09: [Per Jan. 10 CR]

- Support Documents
 - 10/12/09: DSMC Report - Fall 2009
 - 05/01/09: Study Progress Report - Fall 2009

COG-AREN0321

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-ARET0332

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

COG-ARST0332

Continuing Review (CR): Continuing Review January 2010

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/07/09)



- Correspondence
 - 01/22/10: CIRB Continuing Review Approval Letter (Protocol Version Date 04/07/09)
 - 12/07/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 04/07/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 04/07/09 [Per Jan. 10 CR]
- Support Documents
 - 10/12/09: DSMC Report - Fall 2009
 - 09/08/09: Study Progress Report - Fall 2009

COG-ARST0531

Continuing Review (CR): Continuing Review December 2009

Documents Posted:

- Minutes
 - 12/10/09: Minutes - Continuing Review

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

Serious Adverse Events Posted:

Adult Studies

Documents Posted:

- NONE

Pediatric Studies

Study Number: COG AALL07P4

**SAE Posted:
2009EN000149 FU4
2009EN000261
2009EN000264**

Study Number: COG ADVL0525

SAE Posted:



CA200908001321 FU1
DE200908003904 FU1
DE200909002913
DE200909003808
DE200910000090
EG200909002430
ES200909001420 FU1
FI200909001857
FR200905001004 FU4
FR200908000893 FU1
FR200909002562
GR200907003375 FU1
IN200908004325 FU1
IN200908005830 FU1
IT200910000033
JP200908004215 FU1
JP200909000713 FU1
JP200909002768
NL200909006010
TR200909006004
TR200910000016
US200908004261 FU1
US200908006209 FU1
US200909002533
US200909003314
US200909003468
US200909004665
US200909004665 FU1

Corrections to Previous Postings:

Adult Studies

SWOG-S0309

Continuing Review December 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/12/07)

- Correction:

An incorrect version of the Continuing Review Application for the December 2009 Review was replaced with the correct version.



Pediatric Studies

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 or call the CIRB HelpDesk toll-free at 1-(888) 657-3711.