



NCI Central IRB Website Postings Summary

August 1, 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 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

1. Please note the new name, "Website Postings Summary", replaces the current "Study Activity Update" to clarify the intent of this communication.
 2. A Local Site Handbook has been developed as a reference document to assist institutions, local Institutional Review Boards, investigators and research staff in understanding the purpose of the Central Institutional Review Board (CIRB) Initiative and the intended design of this innovative IRB review model. If you would like to view the handbook, please visit our website at the following link:
http://www.ncicirb.org/NCI_Handbook.pdf
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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

CALGB-90601

Initial Review 2009 Approval

Documents Posted:

- Protocol
 - Protocol Version Date 05/22/09
 - Protocol Version Date 03/03/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/22/09 [IR09]
- CIRB Application
 - CIRB Application (Protocol Version Date 05/22/09)
 - CIRB Application (Protocol Version Date 03/03/09)
- Primary Reviews
 - 06/04/09: Primary Reviewer 1 Comments
 - 06/04/09: Primary Reviewer 2 Comments
 - 04/20/09: Primary Reviewer 1 Comments
 - 04/20/09: Primary Reviewer 4 Comments
 - 04/20/09: Pharmacist Comments
- Correspondence
 - 06/11/09: CIRB Final Outcome Letter (Protocol Version Date 05/22/09)
 - 05/22/09: Change Memo (Protocol Version Date 05/22/09)
 - 04/27/09: CIRB Approval Pending Modifications (Protocol Version Date 03/03/09)
- Minutes
 - 06/04/09: Minutes – Group Response to Initial Review
 - 04/20/09: Minutes - Initial Review



- Support Documents
 - 05/27/09: The Oncologist - Neuro-Oncology
 - Hoosier Oncology Group Demonstration

GOG-0252

Initial Review 2009 Approval

Documents Posted:

- Protocol
 - Protocol Version Date 06/12/09
 - Protocol Version Date 06/12/09 Highlighted
 - Protocol Version Date 04/21/09
 - Protocol Version Date 04/21/09 (Highlighted)
 - Appendix I: FIGO STAGE GROUPING FOR PRIMARY CARCINOMA OF THE OVARY
 - Appendix II: Congestive Heart Failure – New York Heart Association Criteria
 - Appendix III: Anaphylaxis Precautions
 - Appendix IV: Specimen Procedures
 - Appendix V: NCI/ DCTD Standard Language
 - Appendix VI: BLOOD PRESSURE CHECK CALENDAR
 - Appendix VII: CANCER TRIALS SUPPORT UNIT (CTSUS) PARTICIPATION PROCEDURES
 - Appendix VIII: CTSU SPECIMEN CONSENT FORM
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/12/09
- CIRB Application
 - CIRB Application (Protocol Version Date 06/12/09)
 - CIRB Application (Protocol Version Date 04/21/09)
- Primary Reviews
 - 06/18/08: Primary Reviewer 1 Comments
 - 05/21/09: Primary Reviewer 1 Comments
 - 05/21/09: Primary Reviewer 2 Comments
 - 05/21/09: Primary Reviewer 3 Comments
 - 05/21/09: Primary Reviewer 4 Comments
- Correspondence
 - 07/27/09: Activation Memo
 - 06/25/09: CIRB Initial Review Approval Letter (Protocol Version Date 06/12/09)
 - 06/12/09: Group Response to CIRB



- 05/29/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 04/21/09)

- Minutes
 - 05/21/09: Minutes - Initial Review

RTOG-0825

Initial Review 2008 Approval

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Initial Review

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

Pediatric Studies

Documents Posted:

- NONE

Posted Documents Related to Amendment Reviews:

Adult Studies

ACOSOG-Z1031

****Temporarily Closed to Accrual – Effective August 15, 2009****

Amendment Review: CIRB Acknowledgement-Temporary Suspension of Accrual effective August 15, 2009

Documents Posted:

- Correspondence
 - 07/29/09: CIRB Acknowledgement of Receipt for Temporary Suspension to Accrual effective August 15, 2009
 - 07/09/09: Temporary Suspension to Accrual Memo

CALGB-10603

Amendment Review: Update #1 (Protocol Version Date 01/16/09)

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Update #1



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

CALGB-30607

Amendment Review: CIRB Acknowledgement - Updated Sunitinib Investigator's Brochure Version of May 29, 2009

Documents Posted:

- Correspondence
 - 07/15/09: CIRB Acknowledgment of Receipt of Sunitinib IB Update

Amendment Review: Update #2 (Protocol Version Date 04/29/09)

Documents Posted:

- Minutes
 - 06/04/09: Minutes - Update #2 Review

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

CALGB-80101

Amendment Review: Shortage of Leucovorin

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Leucovorin Shortage

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

CALGB-80405

Amendment Review: Shortage of Leucovorin

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Leucovorin Shortage

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



ECOG-E2603

Amendment Review: CIRB Acknowledgement - Updated Sorafenib Investigator's Brochure Version 10 dated 07/01/09

Documents Posted:

- Correspondence
 - 07/15/09: CIRB Acknowledgement of Receipt of Sorafenib IB update

ECOG-E2805

Amendment Review: CIRB Acknowledgement - Updated Sorafenib Investigator's Brochure Version 10 dated 07/01/09

Documents Posted:

- Correspondence
 - 07/15/09: CIRB Acknowledgement of Receipt of Sorafenib IB update

ECOG-E5103

Amendment Review: Update #4 (Protocol Version Date 07/10/09)

Documents Posted:

- Amendments
 - 07/10/09: Change Memo (Protocol Version Date 07/10/09)
- Correspondence
 - 07/13/09: CIRB Update 4 Approval Letter (Protocol Version Date 07/10/09)
- Protocol
 - Protocol Version Date 07/10/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/10/09 [up4]

ECOG-E5202

Amendment Review: Shortage of Leucovorin

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Leucovorin Shortage

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



Amendment Review: CIRB Approval of Recruitment Materials

Documents Posted:

- Minutes
 - 05/21/09: Minutes - Dear Participant Letter

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

ECOG-E5204

Amendment Review: Shortage of Leucovorin

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Leucovorin Shortage

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

GOG-0249

Amendment Review: Revision #2 (Protocol Version Date 06/10/09)

Documents Posted:

- Amendments
 - 06/10/09: Change Memo (Protocol Version Date 06/10/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 06/10/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/10/09)
- Correspondence
 - 07/22/09: Correction to GOG 0249 Revision #2 Outcome Letter Dated June 16, 2009
 - 06/16/09: CIRB Revision 2 Approval Letter (Protocol Version Date 06/10/09)
- Protocol
 - Protocol Version Date 06/10/09
 - Protocol Version Date 06/10/09 - Highlighted Changes
 - 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 06/10/09 [Am2]

Amendment Review: Update 07/13/09 (Protocol Version Date 06/10/09)

Documents Posted:

- Amendments
 - 07/27/09: Change Memo (Protocol Version Date 06/10/09)
- Correspondence
 - 07/28/09: CIRB Approval Letter for Update of 07/13/09 (Protocol Version 06/10/09)
- Protocol
 - Protocol Version Date 06/10/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/10/09 (Update date 07/13/09)

NCCTG-N0147

Amendment Review: Shortage of Leucovorin

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Leucovorin Shortage

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

NCCTG-N0723

Amendment Review: Addendum #1 (Protocol Version Date 10/28/08)

Documents Posted:

- Minutes
 - 12/15/08: Minutes - Addendum 1

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



RTOG-0320

****Closed to Accrual – Effective August 11, 2009****

Amendment Review: CIRB Acknowledgement-Closure to Accrual effective August 11, 2009

Documents Posted:

- Correspondence
 - 07/29/09: CIRB Acknowledgement of Closure to Accrual
 - Closure to Accrual Memo

RTOG-0825

Amendment Review: Update 04/15/09 (Protocol Version Date 03/16/09)

Documents Posted:

- Amendments
 - 04/15/09: Change Memo (Protocol Version Date 03/16/09)
- Correspondence
 - 07/24/09: CIRB Update 04/15/09 Approval Letter (Protocol Version Date 03/16/09)
- Protocol
 - Protocol Version Date 03/16/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/16/09 (Update 04/15/09)

SWOG-S0307

****Temporarily Closed to Accrual – Effective August 24, 2009****

Amendment Review: CIRB Acknowledgement-Temporary Closure to Accrual effective August 24, 2009

Documents Posted:

- Correspondence
 - 07/28/09: CIRB Acknowledgement of Receipt for Temporary Closure Memo
 - 07/24/09: Temporary Closure to Accrual Memo



Pediatric Studies

COG-AALL07P4

****Temporary Suspension to Accrual - Effective July 28, 2009****

Amendment Review (AR): **Temporary Suspension to Accrual (07/28/09)**

Documents Posted:

- Correspondence
 - 07/29/09: CIRB Acknowledgement of COG AALL07P4 Temporary Suspension to Accrual Memo
 - 07/28/09: COG Notice-Temporary Suspension to Accrual of AALL07P4

COG-ADVL0821

****Reactivation of Accrual for One Additional Patient for Ewing Sarcoma/Peripheral PNET Stratum - Effective July 8, 2009****

Amendment Review (AR): **Re-opening of the Ewing Sarcoma/Peripheral PNET Stratum to Accrual for One Patient (07/08/09)**

Documents Posted:

- Correspondence
 - 07/14/09: CIRB Acknowledgement - ADVL0821 Re-opening of the Ewing Sarcoma/Peripheral PNET Stratum to Accrual for One Patient – Effective July 8, 2009
 - 07/08/09: COG Notice - ADVL0821 Re-opening of the Ewing Sarcoma/Peripheral PNET Stratum to Accrual for One Patient – Effective July 8, 2009

****Partial Closure for Ewing Sarcoma/Peripheral PNET Disease Stratum - Effective July 20, 2009****

Amendment Review (AR): **Partial Closure for ADVL0821 Ewing Sarcoma/Peripheral PNET Disease Stratum (07/20/09)**

Documents Posted:

- Correspondence
 - 07/24/09: CIRB Acknowledgement - ADVL0821 Partial Closure for Ewing Sarcoma/Peripheral PNET Disease Stratum
 - 07/20/09: COG Notice - ADVL0821 Partial Closure for Ewing Sarcoma/Peripheral PNET Disease Stratum

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

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 06/02/09)



- Correspondence
 - 07/24/09: CIRB Acknowledgement of COG ADVL0821 Activation of Amendment #2 (Protocol Version Date 06/02/09)
 - 07/24/09: COG ADVL0821 Amendment #2 Activation Memo
 - 07/15/09: CIRB Approval of COG ADVL0821 Amendment #2 (Protocol Version Date 06/02/09)
 - 06/02/09: COG Change Memo (Protocol Version Date 06/02/09)

- Protocol
 - Protocol Version Date 06/02/09
 - Protocol Version Date 06/02/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/02/09

- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments

Posted Documents Related to Continuing Reviews:

Adult Studies

CALGB-40302

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: 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-80405

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/04/09: 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-E1899

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: 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-E1900

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/04/09: 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-E2905

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: 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-E3999

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: 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-E4599

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: Minutes - Continuing Review

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

GOG-0219

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: Minutes - Continuing Review

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

GOG-0240

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/04/09: Minutes - Continuing Review

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

GOG-0249

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- CIRB Application
 - CIRB Continuing Review Application (Protocol Version Date 06/10/09)
- Correspondence
 - 07/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/10/09)
 - 06/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/10/09



- 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 06/10/09 [CR09]

- Primary Reviews
 - 07/16/09: Primary Reviewer 1 Comments

NSABP-B-40

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/15/08)

- Correspondence
 - 07/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/15/08)
 - 06/30/09: Cover Memo (Protocol Version Date 02/15/08)
 - 06/04/09: Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 02/15/08

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 02/15/08 [CR09]
 - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 02/15/08 [CR09]

- Primary Reviews
 - 07/16/09: Primary Reviewer 1 Comments

- Support Documents
 - 04/17/09: DMC Minutes
 - 10/17/08: DMC Minutes
 - Study Summary



NSABP-B-42

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/04/09: Minutes - Continuing Review

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

RTOG-0415

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: 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-S0023

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: Minutes - Continuing Review
 - 05/21/09: Minutes - Non-Compliance Determination

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

SWOG-S0221

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/07/09: 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-AALL0622

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/22/09)

- Correspondence
 - 07/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/22/09)
 - 06/08/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 01/22/09

- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/22/09

- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments

- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009

COG-AALL07P4

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/02/09)

- Correspondence
 - 07/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/02/09)
 - 06/08/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 04/02/09

- Informed Consent
 - Informed Consent Document for Protocol Version Date 04/02/09



- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments

- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009

COG-AALL08P1

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 12/15/08)

- Correspondence
 - 07/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 12/15/08)
 - 06/08/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 12/15/08

- Informed Consent
 - Informed Consent Document for Protocol Version Date 12/15/08 - Induction Therapy
 - Informed Consent Document for Protocol Version Date 12/15/08 - Post-Induction

- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments

COG-AAML05P1

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/19/09)

- Correspondence
 - 07/16/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/19/09)
 - 06/08/09: CIRB Continuing Review Reminder Notice



- Protocol
 - Protocol Version Date 07/26/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 07/26/07
- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/24/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009

COG-AAML06P1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/11/09: 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-ACCL0431

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/11/09: 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-ACCL05C1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/11/09: 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-ACNS0222

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/11/09: 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-ACNS0621

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/11/09: 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-AEPI05N1

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/22/09)
- Correspondence
 - 07/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/22/09)
 - 06/08/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/22/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/22/09 - Case Subjects
 - Informed Consent Document for Protocol Version Date 01/22/09 - Control Subjects



COG-ALTE05N1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Minutes
 - 06/11/09: 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:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/28/09)
- Correspondence
 - 07/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/28/09)
 - 06/08/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/28/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/28/09 - Induction Therapy
 - Informed Consent Document for Protocol Version Date 01/28/09 - Randomized to Consolidation Therapy
 - Informed Consent Document for Protocol Version Date 01/28/09 - Non-Randomly Consolidation Therapy
- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009
 - 08/25/08: Study Progress Report



COG-ARAR0332

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- CIRB Application
 - CIRB Continuing Review Application (Protocol Version Date 08/30/06)

- Correspondence
 - 07/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/30/06)
 - 07/01/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/30/08)
 - 06/25/09: CIRB Approval Pending Modification Letter (Protocol Version Date 08/30/06)
 - 05/06/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 08/30/06

- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/30/06
 - Informed Consent Document for Protocol Version Date 08/30/06 - Blood Sample
 - Informed Consent Document for Protocol Version Date 08/30/06 - p53 Testing

- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments

- Minutes
 - 06/11/09: Minutes - Continuing Review

- Support Documents
 - 04/03/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009
 - 08/25/08: Study Progress Report

COG-AREN03B2

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 05/23/08)



- Correspondence
 - 07/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/23/08)
 - 06/08/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 05/23/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 05/23/08
- Support Documents
 - 10/07/08: DSMC Report
 - 08/25/08: Study Progress Report

COG-AREN0533

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application - Revised (Protocol Version Date 06/17/08)
 - CIRB Continuing Review Application (Protocol Version Date 06/17/08)
- Correspondence
 - 07/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/17/08)
 - 07/02/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/17/08)
 - 06/25/09: CIRB Approval Pending Modification Letter (Protocol Version Date 06/17/08)
 - 05/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/17/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/17/08
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments
- Minutes
 - 06/11/09: Minutes - Continuing Review



- Support Documents
 - 10/07/08: DSMC Report
 - 08/25/08: Study Progress Report

COG-ARET0231

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/26/08)
- Correspondence
 - 07/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/08)
 - 06/08/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/26/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/26/08
- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments
- Support Documents
 - 04/03/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009
 - 08/25/08: Study Progress Report

COG-ASCT0431

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/05/08)
- Correspondence
 - 07/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/05/08)
 - 06/08/09: CIRB Continuing Review Reminder Notice



- Protocol
 - Protocol Version Date 09/05/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 09/05/08
- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009
 - 08/25/08: Study Progress Report

Serious Adverse Events Posted

Adult Studies

ECOG E1105

SAEs Posted:

1133874
1293580
1329128
1391765
1419144
1836781

ECOG E2100

SAEs Posted:

1133874
1293580
1329128
1391765
1419144
1836781

ECOG E4599

SAEs Posted:

1133874
1201753
1293580



1324148 FU1
1329128
1360351
1391765
1419144
1433885 FU1
1475911 FU1
1836781
1951869 FU1

ECOG E5103

SAEs Posted:

1133874
1293580
1329128
1391765
1419144
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ECOG E5202

SAEs Posted:

1133874
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ECOG E5204

SAEs Posted:

1133874
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267119 FU2

NSABP B-34

SAEs Posted:

200917399 SU128 Fu1
200918353 SU129



200919383 SU131
200919936 SU132 FU1
200920113 SU130
200920420 SU133
200920427 SU134
DE-2006-032513 SU41 FU6

NSABP B-38

SAEs Posted:

DE200904005913
JP200904002325
US200904002663 Fu1
US200904005208

NSABP B-40

SAEs Posted:

250243 FU1
264828 FU4
273064 Fu2
276863 FU1
DE200904005913
JP200904002325
US200904002663 FU1
US200904005208

RTOG 0825

SAEs Posted:

1158823 FU1
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1201753 FU1
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1333814
1360351 FU1
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1718620 FU1
1881593 FU1
1950915
1968432 FU1



Pediatric Studies

COG AALL0631

SAEs Posted:

2009002398
2009002398 FU1
US024762
US024762 FU2
US025340
US025340 FU1
US025340 FU2

COG AALL07P4

SAEs Posted:

2009EN000010 FU3
2009EN000023 FU1
2009EN000047 FU2
2009EN000117 FU1
2009EN000117 FU2
2009EN000131
2009EN000132

COG AAML06P1

SAEs Posted:

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2009002398 FU1
US024762
US024762 FU1
US024762 FU2
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US025340 FU2

COG ADVL0221

SAEs Posted:

DE-JNJFOC-20090304367
ES-JNJFOC-20090202366 FU3
IE-JNJFOC-20090306408
IN-JNJFOC-20090301053 FU1
IN-JNJFOC-20090301053 FU2
IN-JNJFOC-20090301053 FU3
IN-JNJFOC-20090301053 FU4
IN-JNJFOC-20090302921
IN-JNJFOC-20090302921 FU1



IN-JNJFOC-20090302921 FU3
US-JNJFOC_20090103685 FU1
US-JNJFOC-20080403865 FU3
US-JNJFOC-20080502379 FU3
US-JNJFOC-20081205906 FU1
US-JNJFOC-20090102891 FU2
US-JNJFOC-20090404011

COG AEWS0521

SAEs Posted:

1277486
1994045

Corrections to Previous Postings

Adult Studies

Documents Posted:
Correction:

- None

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.