



NCI Central IRB Website Postings Summary

November 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 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

SWOG S0307

A revised Informed Consent Document has been posted to the CIRB website for SWOG S0307 incorporating changes regarding Arm 3 per the SWOG Memo dated October 1, 2009. Sites who have accepted Facilitated Review for SWOG S0307 should use this updated ICD.

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



ECOG-E1208

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 10/28/09
 - Protocol Version Date 06/22/09

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 10/28/09

- CIRB Application
 - CIRB Application (Protocol Version Date 10/28/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 10/28/09)
 - CIRB Application (Protocol Version Date 06/22/09)

- Primary Reviews
 - 08/20/09: Primary Reviewer 1 Comments
 - 08/20/09: Primary Reviewer 2 Comments
 - 08/20/09: Primary Reviewer 4 Comments

- Correspondence
 - 11/09/09: CIRB Update 1 Approval Letter (Protocol Version Date 10/28/09)
 - 10/28/09: ECOG Activation Notice
 - 10/28/09: ECOG Change Memo (Protocol Version Date 10/28/09)
 - 09/29/09: CIRB Final Approval Letter (Protocol Version Date 06/22/09 CIRB Version Date 09/24/09)
 - 09/22/09: ECOG Change Memo (Protocol Version Date 06/22/09)
 - 08/27/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 06/22/09)

- Minutes
 - 08/20/09: Minutes - Initial Review

GOG-0250

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 09/23/09
 - Protocol Version Date 09/23/09 - Highlighted Changes



- Protocol Version Date 06/04/09
- Protocol Version Date 06/04/09 - Highlighted Changes
- Protocol Version Date 04/17/09
- Appendix I: Clinical Staging - Carcinoma of the Corpus Uteri
- Appendix II: NCI/ DCTD Standard Protocol Language
- Appendix III: Specimen Procedures
- Appendix IV: Congestive Heart Failure
- Appendix V: Anaphylaxis Precautions
- Appendix V: Anaphylaxis Precautions - Highlighted Changes
- Appendix VI: Patient Pill Calendar and Patient G-CSF Calendar
- Appendix VI: Patient Pill Calendar and Patient G-CSF Calendar - Highlighted Changes
- Appendix VII: Blood Pressure Check Calendar
- Appendix VII: Blood Pressure Check Calendar - Highlighted Changes

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/23/09

- CIRB Application
 - CIRB Application (Protocol Version Date 09/23/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/23/09)
 - CIRB Application (Protocol Version Date 06/04/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/04/09)
 - CIRB Application (Protocol Version Date 04/17/09)

- Primary Reviews
 - 10/15/09: Primary Reviewer 1 Comments
 - 06/18/08: Primary Reviewer 1 Comments
 - 06/18/08: Primary Reviewer 2 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
 - 11/10/09: CIRB Acknowledgement of GOG 0250 Activation to Accrual
 - 11/09/09: GOG Activation Memo
 - 10/16/09: CIRB Approval Letter Preactivation Revision (Protocol Version Date 09/23/09)
 - 06/19/09: CIRB Final Approval Letter (Protocol Version Date 06/04/09)



- 06/04/09: Change Memo (Protocol Version Date 06/04/09)
- 05/29/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 04/17/09)
- Minutes
 - 10/15/09: Minutes - Revision Prior to Activation
 - 06/18/09: Minutes - Group Response to Initial Review
 - 05/21/09: Minutes - Initial Review

RTOG-0920

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 10/12/09
 - Protocol Version Date 10/12/09 - Highlighted Changes
 - Protocol Version Date 08/24/09
 - Protocol Version Date 08/24/09 - Highlighted Changes
 - Protocol Version Date 07/06/09
 - Protocol Version Date 07/06/09 - Highlighted Changes
 - Protocol Version Date 05/15/09
 - Protocol Version Date 03/05/09
 - Protocol Version Date 03/05/09 - Highlighted Changes
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 10/12/09
- CIRB Application
 - CIRB Application (Protocol Version Date 10/12/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 10/12/09)
 - CIRB Application (Protocol Version Date 08/24/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/24/09)
 - CIRB Application (Protocol Version Date 07/06/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/06/09)
 - CIRB Application (Protocol Version Date 03/05/09)
- Primary Reviews
 - 06/18/08: Primary Reviewer 1 Comments
 - 06/18/08: Primary Reviewer 2 Comments
 - 04/20/09: Primary Reviewer 2 Comments
 - 04/20/09: Primary Reviewer 4 Comments
 - 04/20/09: Pharmacist Comments



- Correspondence
 - 11/09/09: CIRB Acknowledgement of Activation to Accrual
 - 11/05/09: RTOG Activation Broadcast
 - 10/20/09: CIRB Approval of Preactivation Revision 2
 - 10/12/09: RTOG Change Memo (Protocol Version Date 10/12/09)
 - 10/12/09: RTOG Cover Memo
 - 08/27/09: CIRB Approval of Preactivation Revision 1
 - 08/24/09: RTOG Change Memo (Protocol Version Date 08/24/09)
 - 08/24/09: RTOG Cover Memo
 - 07/10/09: CIRB Final Approval Letter (Protocol Version Date 07/06/09)
 - 07/06/09: RTOG Response to CIRB
 - 06/29/09: CIRB Approval Pending Modification (Protocol Version Date 06/02/09)
 - 05/15/09: RTOG Change Memo (Protocol Version Date 05/15/09)
 - 04/27/09: CIRB Approval Pending Modifications (Protocol Version Date 03/05/09)

- Minutes
 - 06/18/09: Minutes - Group Response to Initial Review
 - 04/20/09: Minutes - Initial Review

- Support Documents
 - Phase III Head and Neck Cancer Dermatology Life Quality Index (DLQI)
 - Phase III Head and Neck Cancer Miscellaneous Patient Assessment Form
 - Phase III Head and Neck Cancer The Health Utility Measurement Euro (EQ-5D)
 - Phase III Head and Neck Cancer The University of Michigan Xerostomia
 - Phase III Head and Neck Cancer Therapy General (FACT-H&N)

Pediatric Studies

NONE

Posted Documents Related to Amendment Reviews:

Adult Studies



ECOG-E1A00

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Thalidomide Investigator's Brochure Version 9

ECOG-E1A05

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Revlimid Investigator's Brochure Version 12

ECOG-E1A06

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure Version 12

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Revlimid Investigator's Brochure Version 12

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure Version 9

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Revlimid Investigator's Brochure Version 9

ECOG-E4A03

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Thalidomide Investigator's Brochure Version 9

ECOG-E1305



Amendment Review (AR): Addendum #3 (Protocol Version Date 10/06/09)

Documents Posted:

- Amendments
 - 10/06/09: ECOG Change Memo (Protocol Version Date 10/06/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 10/06/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 10/06/09)
- Correspondence
 - 10/16/09: CIRB Addendum 3 Approval Letter (Protocol Version Date 10/06/09)
- Protocol
 - Protocol Version Date 10/06/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 10/06/09 [Add3]

ECOG-E2805

Amendment Review (AR): Update #4 (Protocol Version Date 10/28/09)

Documents Posted:

- Amendments
 - 10/28/09: ECOG Change Memo (Protocol Version Date 10/28/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 10/28/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 10/28/09)
- Correspondence
 - 11/04/09: CIRB Update 4 Approval Letter (Protocol Version Date 10/28/09)
- Protocol
 - Protocol Version Date 10/28/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 10/28/09 [up4]

ECOG-E2905



Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Revlimid Investigator's Brochure Version 12

GOG-0198

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Thalidomide Investigator's Brochure Version 9

GOG-0240

Amendment Review (AR): Revision #1 (Protocol Version Date 09/24/09)

Documents Posted:

- Amendments
 - 09/24/09: Change Memo (Protocol Version Date 09/24/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/24/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/24/09)
- Correspondence
 - 10/27/09: CIRB Revision 1 Approval Letter (Protocol Version Date 09/24/09)
- Protocol
 - Protocol Version Date 09/24/09
 - Protocol Version Date 09/24/09 - Highlighted Changes
 - Appendix I: Clinical Staging - Carcinoma fo the Cervix Uteri
 - Appendix II: Congestive Heart Failure – New York Heart Association Criteria
 - Appendix III: Specimen Procedures
 - Appendix III: Specimen Procedures - Highlighted Changes
 - Appendix IV: Smoking History Questionnaire
 - Appendix V: NCI Standard Protocol Language
 - Appendix VI: CTSU Participation Procedures
- Informed Consent



- CIRB's Informed Consent Document for Protocol Version Date 09/24/09 [Rev 1]
- Primary Reviews
 - 10/22/09: Primary Reviewer 1 Comments
- Minutes
 - 10/22/09: Minutes - Amendment Review

GOG-0249

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

Documents Posted:

- Amendments
 - 10/09/09: GOG Change Memo (Protocol Version Date 10/09/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 10/09/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 10/09/09)
- Correspondence
 - 10/20/09: CIRB Revision 5 Approval Letter (Protocol Version Date 10/09/09)
- Protocol
 - Protocol Version Date 10/09/09
 - Protocol Version Date 10/09/09 - Highlighted Changes
 - Appendix I: Clinical Staging - Carcinoma of the Corpus Uteri
 - Appendix II: Specimen Procedures
 - Appendix III: Logistical Guidelines for CTSU & CTSU Enrolling Sites
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 10/09/09 [Rev5]

GOG-0252

Amendment Review (AR): Revision #1 (Protocol Version Date 09/23/09)

Documents Posted:

- Amendments
 - 09/23/09: Change Memo (Protocol Version Date 09/23/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/23/09)



- Summary of CIRB Application Revisions (Protocol Version Date 09/23/09)
- Correspondence
 - 10/27/09: CIRB Approval Letter Revision 1 (Protocol Version Date 09/23/09)
- Protocol
 - Protocol Version Date 09/23/09
 - Protocol Version Date 09/23/09 - Highlighted Changes
 - Appendix I: FIGO Stage Grouping for Primary Carcinoma fo 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: CTSU Participation Procedures
 - Appendix VIII: CTSU Specimen Consent Form
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/23/09 [Rev1]
- Primary Reviews
 - 10/22/09: Primary Reviewer 1 Comments
- Minutes
 - 10/22/09: Minutes - Amendment Review

RTOG-0415

****Closed to Accrual - effective November 6, 2009****

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

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgement of RTOG 0415 Closure to Patient Accrual
 - 10/22/09: RTOG Closure to Accrual

RTOG-0534

Amendment Review (AR): Update 10/22/09 (Protocol Version Date 01/08/09)

Documents Posted:



- Amendments
 - 10/22/09: RTOG Change Memo for 10/22/09 Update (Protocol Version Date 01/08/09)
- Correspondence
 - 11/2/09: CIRB Update of 10/22/09 Approval Letter (Protocol Version Date 01/08/09)
- Protocol
 - Protocol Version Date 01/08/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 01/08/09 (up102209)

RTOG-0617

Amendment Review (AR): Amendment #4 (Protocol Version Date 09/22/09)

Documents Posted:

- Amendments
 - 09/22/09: RTOG Change Memo (Protocol Version Date 09/22/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/22/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/22/09)
- Correspondence
 - 10/09/09: CIRB Amendment 4 Approval Letter (Protocol Version Date 09/22/09)
- Protocol
 - Protocol Version Date 09/22/09
 - Protocol Version Date 09/22/09 - Highlighted Changes
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/22/09 [Am4]

Amendment Review (AR): Update 10/29/09 (Protocol Version Date 09/22/09)

Documents Posted:

- Amendments
 - 10/29/09: RTOG Change Memo (Protocol Version Date 09/22/09)



- Correspondence
 - 10/30/09: CIRB Update of 10/29/09 Approval Letter (Protocol Version Date 09/22/09)
- Protocol
 - Protocol Version Date 09/22/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/22/09 [up102909]

RTOG-0825

Amendment Review (AR): CIRB Approval of the Recruitment Materials

Documents Posted:

- Correspondence
 - 08/18/09: CIRB Approval of the Recruitment Materials
 - 07/08/09: CIRB Approval Pending Modifications of Recruitment Material
- Support Documents
 - Recruitment Brochure
 - Recruitment Flyer
- Primary Reviews
 - 06/18/09: Primary Reviewer 1 Comments
- Minutes
 - 06/18/09: Minutes - Patient Brochure & Flyer

SWOG-S0307

Amendment Review (AR): SWOG Informed Consent Document Clarification Memo

Documents Posted:

- Correspondence
 - 10/01/09: SWOG S0307 Informed Consent Clarification Memo
 - 11/09/09: CIRB Approval Letter of SWOG S0307 Informed Consent Document Addition
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/13/09 (CIRB Version Date 11/09/09)

SWOG-S0777



Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure

Documents Posted:

- Correspondence
 - 10/30/09: CIRB Acknowledgment - Updated Revlimid Investigator's Brochure Version 12

Pediatric Studies

COG-ADVL0525

****Closed to Accrual by COG - Effective October 26, 2009****

Amendment Review (AR): **CIRB Acknowledgement of COG-ADVL0525 Study Closure (10/26/09)**

Documents Posted:

- Correspondence
 - 11/02/09: CIRB Acknowledgement of ADVL0525 Study Closure
 - 10/26/09: COG-ADVL0525 Closure to Patient Accrual - Effective October 26, 2009
- Informed Consent
 - Informed Consent Document for Protocol Version Date 05/07/08

COG-AHOD03P1

Amendment Review (AR): Amendment #1A (Protocol Version Date 09/30/2009)

Documents Posted:

- Correspondence
 - 10/30/09: COG-AHOD03P1 Amendment #1A Activation Memo - Revised

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

COG-AHOD0521

****Closed to Accrual by COG - Effective October 30, 2009****

Amendment Review (AR): **CIRB Acknowledgement of COG-AHOD0521 Study Closure (10/30/09)**

Documents Posted:

- Correspondence
 - 11/02/09: CIRB Acknowledgement of AHOD0521 Study Closure
 - 10/30/09: COG-AHOD0521 Closure to Patient Accrual - Effective October 30, 2009



- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/27/09

Posted Documents Related to Continuing Reviews:

Adult Studies

CALGB-30506

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Minutes
 - 10/22/09: Minutes - Continuing Review

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

ECOG-E1A05

Continuing Review (CR): Continuing Review November 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 07/08/09)
- Correspondence
 - 11/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/08/09)
 - 09/09/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 07/08/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/08/09 [CR09]
- Support Documents
 - November 2009 - Study Summary
 - April 2009 - DMC Recommendations
- Primary Reviews
 - 11/05/09: Primary Reviewer 1 Comments



NCCTG-N0147

Continuing Review (CR): Continuing Review November 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/21/09)
- Correspondence
 - 11/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/21/09)
 - 10/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 04/21/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 04/21/09 [CR09]
- Support Documents
 - 09/23/09: DMC Meeting
 - September 2009 - Study Summary
- Primary Reviews
 - 11/05/09: Primary Reviewer 1 Comments

NCIC CTG-BR.19

Continuing Review (CR): Continuing Review November 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/03/05)
- Correspondence
 - 11/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/03/05)
 - 11/03/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/03/05
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 01/03/05 [CR09]



- Support Documents
 - Spring 2009 - Study Summary

NCIC CTG-MA.27

Continuing Review (CR): Continuing Review November 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 03/06/09 [Companion] & 03/09/09 [Non-Companion])
- Correspondence
 - 11/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/06/09 and 03/09/09)
 - 09/09/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 03/06/09 [Companion]
 - Protocol Version Date 03/09/09 [Non-Companion]
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/06/09 [CR09]: Companion
 - CIRB's Informed Consent Document for Protocol Version Date 03/09/09 [CR09]: Non-Companion
- Primary Reviews
 - 11/05/09: Primary Reviewer 1 Comments
- Support Documents
 - 05/01/09: DSMC Summary Report
 - Spring 2009 - Study Summary

NSABP-B-43

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Minutes
 - 10/15/09: Minutes - Continuing Review

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



Pediatric Studies

COG-AALL03B1

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 11/14/08)

- Correspondence
 - 11/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/14/08)
 - 10/06/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 11/14/08

- Informed Consent
 - Informed Consent Document for Protocol Version Date 11/14/08 [Per Oct. 09 CR]: Additional Bone Marrow
 - Informed Consent Document for Protocol Version Date 11/14/08 [Per Oct. 09 CR]: Study Entry And Shipment Of Samples

- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - 11/01/08: Study Progress Report - Spring 2009

COG-ACNS0423

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

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

- Correspondence
 - 10/29/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
 - 09/08/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 02/12/07

- Informed Consent



- Informed Consent Document for Protocol Version Date 02/12/07 [Per Oct. 09 CR]
- Support Documents
 - 11/01/08: Study Progress Report - Spring 2009
 - 10/07/08: DSMC Report - Fall 2008

COG-ANBL00B1

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 08/06/07)
- Correspondence
 - 11/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/07)
 - 10/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 08/06/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/06/07 [Per Oct. 09 CR]
- Support Documents
 - 05/01/09: Study Progress Report - Fall 2009

COG-ANHL04B1

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 08/03/07)
- Correspondence
 - 11/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/03/07)
 - 10/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 08/03/07



- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/03/07 [Per Oct. 09 CR]
- Support Documents
 - 11/01/08: Study Progress Report - Spring 2009

COG-D9902

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 07/24/08)
- Correspondence
 - 11/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/24/08)
 - 10/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 07/24/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 07/24/08 [Per Oct. 09 CR]
- Support Documents
 - 05/01/09: Study Progress Report - Fall 2009

Serious Adverse Events Posted

Adult Studies

CALGB 40502

SAE Posted:
1232396 FU1
1257729 FU1
1293580 FU1
1329128 FU1
1613977
1833568 FU1
1836781 FU1



CALGB 40503

SAE Posted:
1232396 FU1
1257729 FU1
1293580 FU1
1314985 FU1
1329128 FU1
1613977
1833568 FU1
1836781 FU1
1839475 FU1
1994045 FU1

ECOG E3201

SAE Posted:
1265048
1265048 FU1

ECOG E4599

SAE Posted:
1158823 FU1
1192440
1201753 FU1
1202538
1232396
1257729
1333814
1360351 FU1
1390754
1390754 FU1
1392926
1718620 and 1718620 FU1 (corrected report)
1833568
1881593 FU1
1950915
1968432 FU1
1987521 FU1

NSABP B-34

SAE Posted:
SU 120 FU2



NSABP C-08

**SAE Posted:
1881593 FU1
1987521 FU1**

RTOG 0522

**SAE Posted:
09-02-16049 FU2
09-02-16746 FU1 - DDL 338-fu01
09-02-16881 Fu1
09-02-16987 - DDL 341**

SWOG S0307

**SAE Posted:
200916296 SU123 FU1
200920420 SU133 FU2
200923557 SU148
200924334 SU149
200924334 SU149 FU1**

SWOG S0502

**SAE Posted:
1133874 FU1
1809441 FU1
1839475
1839475 FU1**

SWOG S0518

**SAE Posted:
1133874 FU1
1687519
1809441 FU1
1839475**

SWOG S0600

**SAE Posted:
1133874 FU1
1809441 FU1
1839475**



Pediatric Studies

None

Corrections to Previous Postings

Adult Studies

NONE

Pediatric Studies

None

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