



NCI Central IRB Website Postings Summary

October 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

- 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

<u>ECOG-E3F05</u>

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 09/11/09
 - Protocol Version Date 08/03/09



- Protocol Version Date 03/25/09
- Protocol Version Date 12/04/07
- Protocol Version Date 08/31/07
- Protocol Version Date 03/19/07

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/11/09

- CIRB Application
 - CIRB Application (Protocol Version Date 09/11/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/11/09)
 - CIRB Application (Protocol Version Date 08/03/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/03/09)
 - CIRB Application (Protocol Version Date 03/25/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 03/25/09)
 - CIRB Application (Protocol Version Date 12/04/07)
 - Summary of CIRB Application Revisions (Protocol Version Date 12/04/07)
 - CIRB Application (Protocol Version Date 08/31/07)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/31/07)
 - CIRB Application (Protocol Version Date 03/19/07)

- Primary Reviews
 - 10/05/07: Primary Reviewer 1 Comments
 - 10/05/07: Primary Reviewer 2 Comments

- Correspondence
 - 09/17/09: CIRB Pre-Activation Update 1 Approval
 - 09/11/09: ECOG Activation Notice
 - 09/11/09: Change Memo (Protocol Version Date 09/11/09)
 - 08/20/09: CIRB Pre-Activation Addendum 2 Approval
 - 04/30/09: CIRB Pre-Activation Addendum 1 Approval
 - 12/26/07: CIRB Initial Review Approval
 - 11/07/07: CIRB Approval Pending Modification
 - 07/09/07: CIRB Table of Initial Review

- Minutes
 - 04/20/09: Minutes - Addendum 1
 - 10/05/07: Minutes - Group Response to Initial Review
 - 06/18/07: Minutes - Initial Review



- Support Documents
 - Demographically Based Index of Premorbid Intelligence (Formula & QOL Form)

GOG-0219

Initial Review (IR): 2009

Documents Posted:

- Minutes
 - 08/06/09: Minutes - Group Response to initial Review

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

GOG-0261

Initial Review (IR): 2009

Documents Posted:

- Minutes
 - 09/03/09: Minutes – Group Response to Initial Review

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

NCCTG-N0577

Initial Review (IR): 2009

(Continuing Review, September 2009 posted in conjunction with this action)

Documents Posted:

- Protocol
 - Protocol Version Date 06/26/09
 - Protocol Version Date 03/12/09
 - Protocol Version Date 01/26/09
 - Protocol Version Date 11/18/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/26/09
- CIRB Application
 - CIRB Application (Protocol Version Date 06/26/09)
 - CIRB Application (Protocol Version Date 03/12/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 03/12/09)
 - CIRB Application (Protocol Version Date 01/26/09)



- Summary of CIRB Application Revisions (Protocol Version Date 01/26/09)
- CIRB Application (Protocol Version Date 11/18/08)
- Summary of CIRB Application Revisions (Protocol Version Date 11/18/08)

- Primary Reviews
 - 12/15/08: Primary Reviewer 1 Comments
 - 12/15/08: Primary Reviewer 2 Comments
 - 12/15/08: Primary Reviewer 3 Comments
 - 12/15/08: Primary Reviewer 4 Comments
 - 12/15/08: Pharmacist Comments

- Correspondence
 - 09/22/09: NCCTG Activation Notice
 - 07/17/09: CIRB Approval - Pre-Activation Amendment #1
 - 03/27/09: CIRB Approval - Revision Prior to Activation
 - 02/09/09: CIRB Final Approval Letter (Protocol Version Date 01/26/09)
 - 01/26/09: NCCTG Response to CIRB
 - 12/23/08: CIRB Approval Pending Modification (Updated)
 - 12/22/08: CIRB Approval Pending Modification

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

- Support Documents
 - NCCTG Preregistration Screening Failure Form

RTOG-0724

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 09/03/09
 - Protocol Version Date 09/03/09 - Highlighted Changes
 - Protocol Version Date 07/27/09

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/03/09 [IR]

- CIRB Application
 - CIRB Application (Protocol Version Date 09/03/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/03/09)



- CIRB Application (Protocol Version Date 07/27/09)
- Primary Reviews
 - 08/20/09: Primary Reviewer 1 Comments
 - 08/20/09: Primary Reviewer 2 Comments
 - 08/20/09: Primary Reviewer 3 Comments
- Correspondence
 - 09/16/09: Activation Notice
 - 09/08/09: CIRB Final Approval Letter (Protocol Version Date 09/03/09)
 - 09/03/09: RTOG Cover Memo
 - 08/27/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 07/27/09)
- Minutes
 - 08/20/09: Minutes - Initial Review
- Support Documents
 - RTOG Quality of Life Form

RTOG-0815

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 08/17/09
 - Protocol Version Date 08/17/09 - Highlighted Changes
 - Protocol Version Date 07/22/09
 - Protocol Version Date 07/22/09 - Highlighted Changes
 - Protocol Version Date 05/19/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/17/09 [IR]
- CIRB Application
 - CIRB Application (Protocol Version Date 08/17/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/17/09)
 - CIRB Application (Protocol Version Date 07/22/09)
 - CIRB Application (Protocol Version Date 07/22/09) - Highlighted Changes
 - Summary of CIRB Application Revisions (Protocol Version Date 07/22/09)



- Summary of CIRB Application Revisions (Protocol Version Date 07/22/09) - Highlighted Changes
- CIRB Application (Protocol Version Date 05/19/09)

- Primary Reviews
 - 07/02/09: Primary Reviewer 1 Comments
 - 07/02/09: Primary Reviewer 2 Comments
 - 07/02/09: Primary Reviewer 3 Comments
 - 07/02/09: Primary Reviewer 4 Comments

- Correspondence
 - 08/21/09: CIRB Preactivation Revision (Protocol Version Date 08/17/09)
 - 08/17/09: Change Memo (Protocol Version Date 08/17/09)
 - 07/23/09: CIRB Final Approval (Protocol Version Date 07/22/09)
 - 07/22/09: RTOG Response to CIRB
 - 07/20/09: CIRB Revised Approval Pending Modifications Letter (Protocol Version Date 05/19/09)
 - 07/10/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 05/19/09)

- Minutes
 - 07/16/09: Minutes - Initial Review
 - 07/02/09: Minutes - Initial Review

Pediatric Studies

COG-AHEP0731

Initial Review (IR): 2009

Documents Posted:

- Protocol
 - Protocol Version Date 06/19/09
 - Protocol Version Date 06/19/09 - Highlighted Changes
 - Protocol Version Date 04/03/09

- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/19/09 - Parental Permission
 - Informed Consent Document for Protocol Version Date 06/19/09 - Stage 1 or 2
 - Informed Consent Document for Protocol Version Date 06/19/09 - Observation

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



- CIRB Application (Protocol Version Date 04/03/09)
- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments
 - 08/13/09: Primary Reviewer 2 Comments
 - 08/13/09: Primary Reviewer 3 Comments
 - 05/14/09: Primary Reviewer 1 Comments
 - 05/14/09: Primary Reviewer 2 Comments
 - 05/14/09: Primary Reviewer 3 Comments
- Correspondence
 - 09/11/09: COG Activation of AHEP0731 Memo
 - 08/18/09: CIRB Final Approval Letter (Protocol Version Date 06/19/09)
 - 06/22/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 04/03/09)
 - 05/29/09: CIRB Approval Pending Modification Letter of Initial Review Letter (Protocol Version Date 04/03/09)
- Minutes
 - 08/13/09: Minutes - Group Response to Initial Review
 - 05/14/09: Minutes - Initial Review

Posted Documents Related to Amendment Reviews:

Adult Studies

CALGB-30607

Amendment Review (AR): Update #3 (Protocol Version Date 09/08/09)

Documents Posted:

- Amendments
 - 09/14/09: Change Memo (Protocol Version Date 09/08/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/08/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/08/09)
- Correspondence
 - 09/16/09: CIRB Update 3 Approval Letter (Protocol Version Date 09/08/09)



- Support Documents
 - OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol
 - Protocol Version Date 09/08/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/08/09 [up3]

CALGB-40302

Amendment Review (AR): Update #4 (Protocol Version Date 08/21/09)

Documents Posted:

- Amendments
 - 10/05/09: Change Memo (Protocol Version Date 08/21/09)
- CIRB Application
 - CIRB Application [2] (Protocol Version Date 08/21/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/21/09)
- Correspondence
 - 09/04/09: CIRB Update 4 Approval Letter (Protocol Version Date 08/21/09)
- Support Documents
 - OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol
 - Protocol Version Date 08/21/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/21/09 [up4RRA]

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure v.9 dtd April 17, 2009

Documents Posted:

- Correspondence
 - 09/23/09: CIRB Acknowledgment - Updated Lapatinib Investigator's Brochure version 9 dated April 17, 2009



CALGB-40502

Amendment Review (AR): CIRB Acknowledgement of Receipt - Updated Ixabepilone Investigator's Brochure v.10 dated 06/01/09

Documents Posted:

- Correspondence
 - 09/17/09: CIRB Acknowledgement - Updated Ixabepilone Investigator's Brochure

CALGB-40601

Amendment Review (AR): Update #1 (Protocol Version Date 09/02/09)

Documents Posted:

- Amendments
 - 10/05/09: Change Memo (Protocol Version Date 09/02/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/02/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/02/09)
- Correspondence
 - 09/10/09: CIRB Update 1 Approval Letter (Protocol Version Date 09/02/09)
- Support Documents
 - OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol
 - Protocol Version Date 09/02/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/02/09 [Up1]

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure v.9 dtd April 17, 2009

Documents Posted:

- Correspondence
 - 09/23/09: CIRB Acknowledgment - Updated Investigator's Brochure version 9 dated April 17, 2009



CALGB-80405

Amendment Review (AR): CIRB Approval - Dear Participant, Dear Investigator, and Cover Memo (Associated with Update 6)

Documents Posted:

- Correspondence
 - 09/17/09: CIRB Approval Letter for Dear Investigator and Dear Participant letters (Memo Date 09/15/09)
 - 09/15/09: Cover Memo for Additional Documents to Update 6
- Support Documents
 - Dear Investigator Letter dated September 15, 2009
 - Dear Participant letter dated September 15, 2009

Amendment Review (AR): Update #6 (Protocol Version Date 08/17/09)

Documents Posted:

- Amendments
 - 09/15/09: Change Memo (Protocol Version Date 08/17/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 08/17/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/17/09)
- Correspondence
 - 09/04/09: CIRB Update 6 Approval Letter (Protocol Version Date 08/17/09)
- Protocol
 - Protocol Version Date 08/17/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/17/09 [up6]
- Primary Reviews
 - 09/03/09: Primary Reviewer 1 Comments
- Minutes
 - 09/03/09: Minutes - Update 6 Review



ECOG-E1A06

Amendment Review (AR): Addendum #3 (Protocol Version Date 09/03/09)

Documents Posted:

- Amendments
 - 09/03/09: Change Memo (Protocol Version Date 09/03/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/03/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/03/09)
- Correspondence
 - 09/25/09: ECOG Activation Memo
 - 09/14/09: CIRB Addendum 3 Approval Letter (Protocol Version Date 09/03/09)
- Protocol
 - Protocol Version Date 09/03/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version 09/03/09 [Add3]

ECOG-E2805

Amendment Review (AR): Addendum #8 (Protocol Version Date 09/02/09)

Documents Posted:

- Amendments
 - 09/02/09: Change Memo (Protocol Version Date 09/02/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/02/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/02/09)
- Correspondence
 - 09/14/09: CIRB Addendum 8 Approval Letter (Protocol Version Date 09/02/09)
- Support Documents
 - OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol
 - Protocol Version Date 09/02/09



- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/02/09 [add8]

ECOG-E2905

Amendment Review (AR): Addendum #1 (Protocol Version Date 08/14/09)

Documents Posted:

- Amendments
 - 08/14/09: Change Memo (Protocol Version Date 08/14/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 08/14/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/14/09)
- Correspondence
 - 10/14/09: ECOG Activation Memo
 - 08/27/09: CIRB Addendum 1 Approval Letter (Protocol Version Date 08/14/09)
- Protocol
 - Protocol Version Date 08/14/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/14/09 [Ad1]

ECOG-E3805

Amendment Review (AR): Update #6 (Protocol Version Date 08/25/09)

Documents Posted:

- Amendments
 - 08/25/09: Change Memo (Protocol Version Date 08/25/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 08/25/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 08/25/09)
- Correspondence
 - 09/02/09: CIRB Update 6 Approval Letter (Protocol Version Date 08/25/09)



- Protocol
 - Protocol Version Date 08/25/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/25/09 [up6]

ECOG-E5103

Amendment Review (AR): ****SUSPENDED – Effective September 24, 2009****

Documents Posted:

Pending CIRB Review 10/01/09

GOG-0209

Amendment Review (AR): Closed to Patient Entry effective April 20, 2009

Documents Posted:

- Correspondence
 - 09/14/09: CIRB Acknowledgment of Receipt of Closure to Accrual

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 (AR): Study Suspended to Patient Entry effective September 1, 2009

Documents Posted:

- Minutes
 - 09/03/09: Minutes - Unanticipated Problem Determination

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

GOG-0258

Amendment Review (AR): Update 08/31/09 (Protocol Version Date 08/05/09)

Documents Posted:

- Amendments
 - 08/31/09: Change Memo (Protocol Version Date 08/05/09)
- Correspondence
 - 09/14/09: CIRB Approval Letter Update of 08/31/09 (Protocol Version Date 08/05/09)



- Protocol
 - Protocol Version Date 08/05/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/05/09 (Up08/31/09)

GOG-0261

Amendment Review (AR): Revision #1 (Protocol Version Date 08/20/09)
Documents Posted:

- Correspondence
 - CIRB Review of GOG 0261 Revision #1 (Protocol Version Date 08/20/09)

NCCTG-N0723

Amendment Review (AR): CIRB Acknowledgement - Updated Investigator's Brochure version 13 dated February 17, 2009

Documents Posted:

- Correspondence
 - 09/24/09: CIRB Acknowledgement of N0723 Updated Erlotinib Investigator's Brochure 13th Edition dated February 17, 2009

NSABP-B-35

Amendment Review (AR): CIRB Acknowledgment - Updated Arimidex Package Insert dated April 30, 2009

Documents Posted:

- Correspondence
 - 09/24/09: CIRB Acknowledgment - Updated Arimidex Package Insert dated April 30, 2009
 - 09/17/09: NSABP US Package Insert Update Notice

NSABP-B-42

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

- Correspondence
 - 09/11/09: Activation Memo for B-42 Amendment 3

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



NSABP-R-04

Amendment Review (AR): CIRB Acknowledgement-Updated Oxaliplatin Investigator's Brochure Version 9 dated 06/2009

Documents Posted:

- Correspondence
 - 09/18/09: CIRB Acknowledgement of NSABP R-04 Updated Oxaliplatin Investigator's Brochure Version 9
 - 08/13/09: NSABP Notice - Updated Oxaliplatin Clinical Investigator's Brochure (Edition: E09, dated June 8, 2009)

RTOG-0320

Amendment Review (AR): CIRB Acknowledgment - Updated Investigator's Brochure v.13 dtd February 17, 2009

Documents Posted

- Correspondence
 - 09/23/09: CIRB Acknowledgment - Updated Investigator's Brochure v.13 dated Feb 17, 2009

RTOG-0436

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

Documents Posted

- Amendments
 - 09/22/09: Change Memo (Protocol Version Date 09/09/09)
- Correspondence
 - 09/23/09: CIRB Update of 09/22/09 Approval Letter (Protocol Version Date 09/09/09)
- Protocol
 - Protocol Version Date 09/09/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/09/09 [up092209]

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

Documents Posted

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



- CIRB Application
 - CIRB Application (Protocol Version Date 09/09/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/09/09)

- Correspondence
 - 09/15/09: CIRB Amendment 2 Approval Letter (Protocol Version Date 09/09/09)
 - 09/09/09: RTOG Cover Memo

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

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/09/09 [Am2]

RTOG-0522

Amendment Review (AR): Update 09/01/09 (Protocol Version Date 08/25/08)

Documents Posted:

- Amendments
 - 09/01/09: Change Memo (Protocol Version Date 08/25/08)

- Correspondence
 - 09/14/09: CIRB Update 09/01/09 Approval Letter (Protocol Version Date 08/25/09)

- Protocol
 - Protocol Version Date 08/25/08

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/25/09 [Up09/01/09]

RTOG-0815

Amendment Review (AR): CIRB Approval-Administrative Updates of 09/14/09 and 09/17/09

Documents Posted:

- Amendments
 - 09/17/09: Change Memo (Protocol Version Date 08/17/09)



- Correspondence
 - 09/18/09: CIRB Approval of 09/14/09 and 09/17/09 Updates (Protocol Version Date 08/17/09)
- Protocol
 - Protocol Version Date 08/17/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/17/09 [Up09/17/09]

SWOG-S0106

Amendment Review (AR): CIRB Acknowledgement - Notification of the Clarification for the Third Registration Requirement

Documents Posted:

- Correspondence
 - 09/29/09: CIRB Acknowledgement of SWOG S0106 Notification of the Clarification for the Third Registration Requirement dated 09/15/09
 - 09/15/09: Notification of the Clarification for the Third Registration Requirement Memo

SWOG-S0307

Amendment Review (AR): CIRB Acknowledgment of Reactivation to Accrual Memo dated 08/24/09

Documents Posted:

- Correspondence
 - 09/22/09: CIRB Acknowledgment of Reactivation to Accrual Memo dated 08/24/09
 - 08/24/09: Reactivation to Accrual Memo effective 09/01/09

Amendment Review (AR): Clodronate Shortage 3

Documents Posted:

- Minutes
 - 09/03/09: Minutes - Unanticipated Problem Determination

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



Pediatric Studies

COG-AALL0631

Amendment Review (AR): Amendment #1A and Reactivation (Protocol Version Date 07/08/2009)

Documents Posted:

- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments

- Minutes
 - 08/13/09: Minutes - Group Response to Amendment Review

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

COG-AALL07P4

**** Study Reactivation by COG - Effective September 21, 2009****

Amendment Review (AR): **CIRB Acknowledgement of COG AALL07P4 Activation of Amendment #2 and Reactivation to Accrual - (09/21/09)**

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 08/07/09)

- Correspondence
 - 09/21/09: Acknowledgement of the Activation of Amendment #2 and Reactivation to Accrual
 - 09/21/09: COG-AALL07P4 Amendment #2 Re-activation Memo
 - 09/15/09: CIRB Approval of COG-AALL07P4 Amendment #2 (Protocol Version Date 08/07/09)
 - 08/07/09: COG Change Memo (Protocol Version Date 08/07/09)

- Protocol
 - Protocol Version Date 08/07/09
 - Protocol Version Date 08/07/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/07/09

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



COG-AAML0531

Amendment Review (AR): Amendment #2 (Protocol Version Date 07/14/2009)

Documents Posted:

- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments

- Minutes
 - 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-AAML05P1

Amendment Review (AR): Amendment #1 Protocol Version Date 08/11/09)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 08/11/09)
 - CIRB Application (Protocol Version Date 06/19/09)
 - CIRB Application (Protocol Version Date 04/07/09)

- Correspondence
 - 09/14/09: COG-AAML05P1 Amendment #1 Activation Memo
 - 09/01/09: CIRB Approval of COG-AAML05P1 Amendment #1 (Protocol Version Date 08/11/09)
 - 08/11/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/19/09)
 - 07/31/09: CIRB Approval Pending Modification Letter (Protocol Version Date 06/19/09)
 - 06/19/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 04/07/09)
 - 05/29/09: CIRB Approval Pending Modification Letter (Protocol Version Date 06/19/09)
 - 04/07/09: COG Change Memo (Protocol Version Date 04/07/09)

- Protocol
 - Protocol Version Date 08/11/09
 - Protocol Version Date 08/11/09 - Highlighted Changes
 - Protocol Version Date 06/19/09
 - Protocol Version Date 06/19/09 - Highlighted Changes
 - Protocol Version Date 04/07/09
 - Protocol Version Date 04/07/09 - Highlighted Changes



- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/11/09
- Primary Reviews
 - 07/09/09: Primary Reviewer 1 Comments
 - 05/14/09: Primary Reviewer 1 Comments
- Minutes
 - 07/09/09: Minutes - Group Response to Amendment Review
 - 05/14/09: Minutes - Amendment Review

COG-ADVL0525

****Partial Closure for Ewing Sarcoma Stratum - Effective September 9, 2009****
Amendment Review (AR): **CIRB Acknowledgement of COG ADVL0525 Ewing Sarcoma Stratum Closure (09/09/09)**

Documents Posted:

- Correspondence
 - 09/15/09: CIRB Acknowledgement: ADVL0525 Partial Closure for Ewing Sarcoma Stratum
 - 09/09/09: COG Notice: ADVL0525 Partial Closure for Ewing Sarcoma Stratum

COG-AHOD04B1

Amendment Review (AR): Amendment #2 (Protocol Version Date 09/21/2009)
(Continuing Review, August 2009 posted in conjunction with this action)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 09/21/09)
- Correspondence
 - 09/28/09: COG-AHOD04B1 Amendment #2 Activation Memo
 - 09/22/09: CIRB Approval of COG-AHOD04B1 Amendment #2 (Protocol Version Date 09/21/09)
 - 09/21/09: COG Change Memo (Protocol Version Date 09/21/09)
- Protocol
 - Protocol Version Date 09/21/09
 - Protocol Version Date 09/21/09 - Highlighted Changes
- Informed Consent
 - Informed Consent Document for Protocol Version Date 09/21/09



COG-ANBL0531

Amendment Review (AR): Amendment #1 (Protocol Version Date 08/14/09)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 08/14/09)

- Correspondence
 - 09/25/09: Correction to ANBL0531 Amendment #1 Approval Outcome Letter
 - 09/21/09: COG-ANBL0531 Amendment #1 Activation Memo
 - 09/15/09: CIRB Approval of COG-ANBL0531 Amendment #1 (Protocol Version Date 08/14/09) - CORRECTION
 - 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 - Initial Therapy
 - Informed Consent Document for Protocol Version Date 08/14/09 - Treatment Group 2
 - Informed Consent Document for Protocol Version Date 08/14/09 - Treatment Group 3
 - Informed Consent Document for Protocol Version Date 08/14/09 - Treatment Group 4
 - Informed Consent Document for Protocol Version Date 08/14/09 - Treatment for Residual or Recurrent

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

COG-AOST0331

Amendment Review (AR): Amendment #3 (Protocol Version Date 08/03/09)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 08/03/09)

- Correspondence
 - 09/14/09: COG-AOST0331 Amendment #3 Activation Memo



- 09/01/09: CIRB Approval of COG-AOST0331 Amendment #3 (Protocol Version Date 08/03/09)
- 08/03/09: COG Change Memo (Protocol Version Date 08/03/09)

- Protocol
 - Protocol Version Date 08/03/09
 - Protocol Version Date 08/03/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/03/09 - Part 1: Induction Therapy
 - Informed Consent Document for Protocol Version Date 08/03/09 - Part 2: Good Response
 - Informed Consent Document for Protocol Version Date 08/03/09 - Part 2: Poor Response

COG-ARET0332

Amendment Review (AR): Amendment #3 (Protocol Version Date 08/03/2009)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 08/03/09)

- Correspondence
 - 09/21/09: COG-ARET0332 Amendment #3 Activation Memo
 - 09/15/09: CIRB Approval of COG-ARET0332 Amendment #3 (Protocol Version Date 08/03/09)
 - 08/03/09: COG Change Memo (Protocol Version Date 08/03/09)

- Protocol
 - Protocol Version Date 08/03/09
 - Protocol Version Date 08/03/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document for Protocol Version Date 08/03/09 - Observation Arm
 - Informed Consent Document for Protocol Version Date 08/03/09 - Chemotherapy Arm

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



COG-ARST03P1

****ADMINISTRATIVELY COMPLETED as of February 28, 2008****

Amendment Review (AR): **Closure of COG-ARST03P1 Due to Study Completion (02/28/08)**

Documents Posted:

- Correspondence
 - 09/29/09: CIRB Closure of COG ARST03P1 Due to Study Completion
 - 02/28/08: Protocol Status Update - ADMINISTRATIVELY COMPLETED

Posted Documents Related to Continuing Reviews:

Adult Studies

ECOG-E3F05

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 03/25/09)
- Correspondence
 - 07/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/25/09)
 - 05/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 03/25/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/25/09 [CR09]
- Support Documents
 - June 2009 - Study Summary

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 12/04/07)
- Correspondence
 - 10/02/08: CIRB Continuing Review Approval Letter (Protocol Version Date 12/04/07)
 - 08/05/08: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 12/04/07
- Informed Consent
 - Informed Consent Document For Protocol Version Date 12/04/07 [CR08]
- Support Documents
 - June 2008 - Study Summary

ECOG-E5202

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

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

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

NCCTG-N0577

Continuing Review (CR): Continuing Review September 2009

(Posted in conjunction with Initial Review 2009)

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/26/09)
- Correspondence
 - 09/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/09)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/26/09



- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/26/09 [CR09]

NSABP-B-33

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

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

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

NSABP-B-39/RTOG-0413

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

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

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

NSABP-R-04

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

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

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

SWOG-S0518

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

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

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



SWOG-S0777

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

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

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

Pediatric Studies

COG-AALL07P1

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/09/09)
- Correspondence
 - 09/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/09/09)
 - 08/05/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 02/09/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 02/09/09
- Primary Reviews
 - 09/10/09: Primary Reviewer 1 Comments

COG-AAML0431

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

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



- Correspondence
 - 09/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/07/07)
 - 09/10/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/07/07)
 - 09/02/09: CIRB Approval Pending Modification Letter (Protocol Version Date 02/07/07)
 - 07/06/09: CIRB Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 02/07/07

- Informed Consent
 - Informed Consent Document for Protocol Version Date 02/07/07

- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments

- Minutes
 - 08/13/09: Minutes - Continuing Review

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

COG-AAML0631

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments

- Minutes
 - 08/13/09: 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-ACNS0232

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/09/08)



- Correspondence
 - 09/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/09/08)
 - 08/05/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/09/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/09/08
- Primary Reviews
 - 09/10/09: Primary Reviewer 1 Comments
- Support Documents
 - 04/03/09: DSMC Report - Spring 2009
 - 11/01/08: Study Progress Report - Spring 2009

COG-ADVL06B1

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 11/29/07)
- Correspondence
 - 09/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/29/07)
 - 09/14/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/29/07)
 - 09/02/09: CIRB Approval Pending Modification Letter (Protocol Version Date 11/29/07)
 - 07/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 11/29/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 11/29/07
- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments



- Minutes
 - 08/13/09: Minutes - Continuing Review
- Support Documents
 - 08/25/08: Study Progress Report - Fall 2008

COG-ADVL0821

Continuing Review (CR): Continuing Review September 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/02/09)
- Correspondence
 - 09/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/02/09)
 - 08/05/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/02/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/02/09
- Primary Reviews
 - 09/10/09: Primary Reviewer 1 Comments

COG-AHOD04B1

Continuing Review (CR): Continuing Review August 2009

(Posted in conjunction with Amendment #2 (Protocol Version Date 09/21/2009))

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/21/09)
 - CIRB Continuing Review Application (Protocol Version Date 04/30/07)
- Correspondence
 - 09/28/09: COG-AHOD04B1 Amendment #2 Activation Memo
 - 09/22/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/21/09)
 - 09/21/09: COG Change Memo (Protocol Version Date 09/21/09)



- 09/02/09: CIRB Approval Pending Modification Letter (Protocol Version Date 04/30/07)
- 07/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 09/21/09
 - Protocol Version Date 09/21/09 - Highlighted Changes
 - Protocol Version Date 04/30/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 09/21/09
- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments
- Minutes
 - 08/13/09: Minutes - Continuing Review
- Support Documents
 - 08/25/08: Study Progress Report - Fall 2008

COG-AHOD0521

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/27/09)
- Correspondence
 - 09/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/27/09)
 - 09/14/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 01/27/09)
 - 09/02/09: CIRB Approval Pending Modification Letter (Protocol Version Date 01/27/09)
 - 07/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/27/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/27/09
- Primary Reviews
 - 08/13/09: Primary Reviewer 1 Comments



- Minutes
 - 08/13/09: Minutes - Continuing Review

- Support Documents
 - 03/24/09: DSMC Report - Spring 2009
 - 11/01/08: Study Progress Report - Spring 2009

Serious Adverse Events Posted

Adult Studies

ACOSOG Z1041

SAEs posted:

1353951

CALGB 40502

SAEs posted:

1133874 FU1

1192440

1201753 FU1

1202538

1232396

1257729

1293580

1329128

1333814

1360351 FU1

1390754

1390754 FU1

1391765

1392926

1419144

1687519

1718620

1789687

1809441 FU1

1833568

1836781

1881593 FU1

1950915



1987521 FU1

CALGB 40503

SAEs posted:

1133874
1133874 FU1
1192440
1201753 FU1
1202538
1232396
1257729
1293580
1329128
1333814
1360351 FU1
1390754
1390754 FU1
1391765
1392926
1419144
1687519
1718620
1809441 FU1
1833568
1836781
1881593 FU1
1950915
1987521 FU1

CALGB 40601

SAEs posted:

Z0000646A

CALGB 80303

SAEs posted:

1133874
1133874 FU1
1192440
1201753 FU1
1232396



1293580
1329128
1333814
1360351 FU1
1390754
1390754 FU1
1391765
1392926
1419144
1687519
1833568
1836781
1950915

CALGB 80405

SAEs posted:

09-02-16834
1133874
1133874 FU1
1192440
1201753 FU1
1202538
1232396
1257729
1265048
1293580
1329128
1333814
1360351 FU1
1390754
1390754 FU1
1391765
1392926
1419144
1687519
1718620
1809441 FU1
1833568
1836781
1881593 FU1
1950915
1987521 FU1



CALGB 90206

SAEs posted:

1133874
1133874 FU1
1192440
1201753 FU1
1232396
1293580
1329128
1333814
1360351 FU1
1390754
1390754 FU1
1391765
1392926
1419144
1687519
1718620
1833568
1836781
1950915

CALGB 90401

SAEs posted:

1133874
1133874 FU1
1192440
1201753 FU1
1202538
1232396
1257729
1293580
1329128
1333814
1360351 FU1
1390754
1390754 FU1
1391765
1392926
1419144
1718620
1687519



1809441 FU1
1833568
1836781
1881593 FU1
1950915
1987521 FU1

ECOG E1305

SAEs posted:

1133874 FU1
1158823 FU1
1192440
1201753 FU1
1202538
1232396
1232396 FU1
1257729
1257729 FU1
1314985 FU1
1329128 FU1
1333814
1360351 FU1
1390754
1390754 FU1
1392926
1438181 FU2
1613977
1687519
1718620 and 1718620 FU1 (corrected report)
1809441 FU1
1833568
1839475
1839475 FU1
1881593 FU1
1950915
1968432 FU1
1987521 FU1
1994045 FU1



ECOG E2805

SAEs posted:

2008013916

Pediatric Studies

None (no Peds meeting during latter half of Sept 2009)

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.