



NCI Central IRB Study Activity Update

February 28, 2009

The CIRB is distributing this study activity update to notify its participating institutions of recent information and documentation for current CIRB protocols. Information about protocol-specific addenda or memoranda issued by the Cooperative Groups, activations/closures of CIRB protocols, drug notices and safety reports, general CIRB memoranda and notices will be included in these broadcast summaries.

The protocol-specific information in this email refers to amendment/revision documentation approved by CIRB and NCI CTEP. Information about new studies refers to protocols that have been approved by the CIRB and NCI CTEP and activated by the Lead Cooperative Group.

These documents are posted within each protocol's document list inside the Participant's Area of the CIRB website (www.ncicirb.org). This is a protected site - you will be required to enter your username and password in order to access the Participant's Area. If you are unsure of your login information or have difficulty accessing the site/documents, please email ncicirbcontact@emmes.com or call the CIRB at 888-657-3711.

General CIRB Documentation

If other individuals at your institution need to receive this email or other CIRB Correspondence please have them email ncicirbcontact@emmes.com with their request.

****Note:** All documentation can be accessed through the What's New section of the CIRB website (<http://www.ncicirb.org>). ******

Protocol Specific Documentation (listed by protocol)

****Note:** All documentation can be accessed through the Participant's Area (http://www.ncicirb.org/CIRB_Login.asp) of the CIRB website. ******



New Initial Approvals Posted:

The new studies listed below have received CIRB approval and are entitled to facilitated review at your local IRB as part of the NCI CIRB initiative. You can download a completed application from the CIRB website along with the documents specified by your local IRB.

Pediatric CIRB Studies

COG-AALL08P1

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 12/15/08
- Protocol Version Date 12/15/08 - Highlighted Changes
- Protocol Version Date 09/11/08
- Protocol Version Date 09/11/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 12/15/08 - Induction Therapy
- Informed Consent Document for Protocol Version Date 12/15/08 - Post-Induction
- CIRB Application (Protocol Version Date 12/15/08)
- CIRB Application (Protocol Version Date 09/11/08)
- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: Primary Reviewer 2 Comments
- 02/23/09: COG Activation AALL08P1 Memo
- 02/20/09: CIRB Acknowledgement of COG AALL08P1 Activation Memo
- 02/06/09: CIRB Final Approval Letter (Protocol Version Date 12/15/08)
- 12/15/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 09/11/08)
- 11/14/08: CIRB Approval Pending Modification of Initial Review Letter (Protocol Version Date 09/11/08)
- 10/16/08: Minutes - Initial Review

COG-AAML08B1

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 01/22/09
- Protocol Version Date 01/22/09 - Highlighted Changes
- Protocol Version Date 10/20/08
- Informed Consent Document for Protocol Version Date 01/22/09
- CIRB Application (Protocol Version Date 01/22/09)
- CIRB Application (Protocol Version Date 10/20/08)
- 12/11/08: Primary Reviewer 1 Comments



- 12/11/08: Primary Reviewer 2 Comments
- 12/11/08: Primary Reviewer 3 Comments
- 02/23/09: COG Activation AAML08B1 Memo
- 02/20/09: CIRB Acknowledgement of COG AAML08B1 Activation Memo
- 02/03/09: CIRB Final Approval Letter (Protocol Version Date 01/22/09)
- 01/26/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/20/08)
- 12/18/08: CIRB Approval Pending Modification of Initial Review Letter (Protocol Version Date 10/20/08)
- 12/11/08: Minutes - Initial Review

Other Activity Posted:

ACOSOG-Z4032

Continuing Review (CR): Approval February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/08/08)
- 02/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/08/08)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 01/08/08
- Informed Consent Document for Protocol Version date 01/08/08 [CR09]
- 01/08/09: DSMB Minutes
- Study Summary
- 02/23/09: Primary Reviewer 1 Comments

ACOSOG-Z6051

Continuing Review (CR): Approval February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/04/08)
- 02/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/04/08)
- 12/03/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/04/08
- Informed Consent Document for Protocol Version Date 06/04/08 [CR09]
- 02/06/09: Primary Reviewer 1 Comments
- 01/08/09: DSMB Report
- December 2008 - Study Summary

CALGB-10501

Amendment Review (AR): Update #2 Approval (Protocol Version Date 12/10/08)

Documents Posted:



- 02/15/09: CALGB Change Memo (Protocol Version Date 12/10/08)
- CIRB Application (Protocol Version Date 12/10/08)
- Summary of CIRB Application Revisions (Protocol Version Date 12/10/08)
- 01/15/09: CIRB Update 2 Approval Letter (Protocol Version Date 12/10/08)
- Protocol Version Date 12/10/08
- Informed Consent Document for Protocol Version Date 12/10/08 [Up2]

CALGB-10603

Amendment Review (AR): Update #1 Approval (Protocol Version Date 01/16/09)
Documents Posted:

- 02/15/09: CALGB Change Memo (Protocol Version Date 01/16/09)
- 12/15/08: CALGB Change Memo (Protocol Version Date 10/24/08)
- CIRB Application (Protocol Version Date 01/16/09)
- CIRB Application (Protocol Version Date 10/24/08)
- Summary of CIRB Application Revisions (Protocol Version Date 10/24/08)
- 01/23/09: CIRB Update 1 Approval Letter (Protocol Version Date 01/16/09)
- 01/12/09: CIRB Approval Pending Modification Update 1
- 02/05/08: CALGB Response to CIRB Modifications
- Protocol Version Date 01/16/09
- Protocol Version Date 10/24/08
- Informed Consent Document for Protocol Version Date 01/16/09 [Up1]

CALGB-40101

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/23/08)
- 02/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/23/08)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 06/23/08
- Informed Consent Document for Protocol Version Date 06/23/08 [CR09]
- 11/14/08: DSMB Recommendations
- November 2008 - Study Summary
- 02/23/09: Primary Reviewer 1 Comments

CALGB-40502

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/04/08)
- 02/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/04/08)



- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 09/04/08
- Informed Consent Document for Protocol Version Date 09/04/08 [CR09]
- 02/23/09: Primary Reviewer 1 Comments

COG-AALL03B1

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/14/08)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/14/08)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/14/08
- Informed Consent Document for Protocol Version Date 11/14/08 - STUDY ENTRY AND SHIPMENT OF SAMPLES
- Informed Consent Document for Protocol Version Date 11/14/08 - ADDITIONAL BONE MARROW
- ASH Abstract 2007

Amendment Review (AR): Amendment #6 (Protocol Version Date 11/14/08)
Documents Posted:

- 12/11/08: Primary Reviewer 1 Comments
- 12/11/08: 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-AALL0331

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/10/08)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/10/08)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/10/08
- Informed Consent Document for Protocol Version Date 10/10/08 - Induction Therapy
- Informed Consent Document for Protocol Version Date 10/10/08 - Standard Risk Low
- Informed Consent Document for Protocol Version Date 10/10/08 - Standard Risk Average



- Informed Consent Document for Protocol Version Date 10/10/08 - Standard Risk High
- Informed Consent Document for Protocol Version Date 10/10/08 - Treatment Changes
- Spring Study Progress Report

COG-AALL0434

Amendment Review (AR): Amendment #3 (Protocol Version Date 10/31/08)
Documents Posted:

- 12/11/08: Primary Reviewer 1 Comments
- 12/11/08: 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-AALL05B1

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/06/07)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/06/07)
- 12/03/08: CIRB continuing Review Reminder Notice
- Protocol Version Date 09/06/07
- Informed Consent Document for Protocol Version Date 09/06/07
- 02/04/08: Study Progress Report

COG-AALL0622

Amendment Review (AR): CIRB Approval of COG AALL0622 Amendment #1 (Protocol Version Date 01/22/09)
Documents Posted:

- CIRB Application (Protocol Version Date 01/22/09)
- 02/20/09: CIRB Acknowledgement of COG AALL0622 Amendment #1 Activation (Protocol Version Date 01/22/09)
- 02/11/09: COG AALL0622 Amendment #1 Approval
- 01/29/09: CIRB Approval of COG AALL0622 Amendment #1 (Protocol Version Date 01/22/09)
- 01/22/09: COG Change Memo (Protocol Version Date 01/22/09)
- Protocol Version Date 01/22/09
- Protocol Version Date 01/22/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/22/09



COG-AAML0431

Continuing Review (CR): Continuing Review November 2008
Documents Posted:

- 11/13/08: Primary Reviewer 1 Comments
- 11/13/08: 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-AAML07P1

Amendment Review (AR): CIRB Approval of AAML07P1 Amendment #1 (Protocol Version Date 01/22/09)
Documents Posted:

- CIRB Application (Protocol Version Date 01/22/09)
- 02/20/09: CIRB Acknowledgement of COG AAML07P1 Amendment #1 Activation (Protocol Version Date 01/22/09)
- 02/11/09: COG AAML07P1 Amendment #1 Approval
- 01/30/09: CIRB Approval of Amendment #1 (Protocol Version Date 01/22/09)
- 01/22/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 12/01/08)
- 01/21/09: CIRB Approval Pending Modification Letter (Protocol Version Date 12/01/08)
- 12/01/08: Change Memo (Protocol Version Date 12/01/08)
- Protocol Version Date 01/22/09
- Protocol Version Date 01/22/09 - Highlighted Changes
- Protocol Version Date 12/01/08
- Protocol Version Date 12/01/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/22/09 - ARM A
- Informed Consent Document for Protocol Version Date 01/22/09 - ARM B
- 01/08/09: Primary Reviewer 1 Comments
- 01/08/09: Minutes - Amendment Review

COG-ACCL05C1

Amendment Review (AR): Amendment #2A (Protocol Version Date 10/31/08)
Documents Posted:

- 12/11/08: Primary Reviewer 1 Comments
- 12/11/08: 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-ACNS0232

Continuing Review (CR): Continuing Review December 2008
Documents Posted:

- 12/11/08: Primary Reviewer 1 Comments
- 12/11/08: 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-ADVL0525

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/07/08)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/07/08)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/07/08
- Informed Consent Document for Protocol Version Date 05/07/08
- 02/12/09: Primary Reviewer 1 Comments
- 08/25/08: Study Progress Report

COG-AEPI05N1

Amendment Review (AR): Amendment #2 (Protocol Version Date 10/30/08)
Documents Posted:

- 12/17/08: Correction Letter for the AEPI05N1 CIRB Approval Letter
- 12/17/08: CIRB Approval Letter (Protocol Version Date 10/30/08) (CORRECTION)
- Informed Consent Document for Protocol Version Date 10/30/08 - CASE SUBJECTS (Correction)
- Informed Consent Document for Protocol Version Date 10/30/08 - CONTROL SUBJECTS (Correction)

Continuing Review (CR): Continuing Review October 2008
Documents Posted:

- 12/17/08: Correction Letter for the AEPI05N1 Continuing Review 2008 Approval Letter
- 12/17/08: CIRB Approval Letter (Protocol Version Date 10/30/08) (CORRECTION)
- Informed Consent Document for Protocol Version Date 10/30/08 - CASE SUBJECTS (Correction)



- Informed Consent Document for Protocol Version Date 10/30/08 - CONTROL SUBJECTS (Correction)

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

COG-AEWS07B1

Continuing Review (CR): Continuing Review December 2008
Documents Posted:

- 12/11/08: Primary Reviewer 1 Comments
- 12/11/08: 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-AHOD03P1

Amendment Review (AR): **CIRB Subpart B Determination for AHOD03P1**
Documents Posted:

- 02/18/09: CIRB Subpart B Determination Memo
- 01/08/09: Primary Reviewer Subpart B Determination
- 01/08/09: Minutes - Subpart B Determination

COG-AHOD04B1

Continuing Review (CR): Continuing Review November 2008
Documents Posted:

- 11/13/08: Primary Reviewer 1 Comments
- 11/13/08: 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-AHOD0521

Amendment Review (AR): CIRB Approval of COG AHOD0521 Amendment #2 (Protocol Version Date 01/27/09)
Documents Posted:

- CIRB Application (Protocol Version Date 01/27/09)
- 02/20/09: CIRB Acknowledgement of COG AHOD0521 Amendment #2 Activation (Protocol Version Date 01/27/09)
- 02/11/09: COG AHOD0521 Amendment #2 Approval
- 02/03/09: CIRB Approval of Amendment #2 (Protocol Version Date 01/27/09)
- 01/27/09: COG Change Memo (Protocol Version Date 01/27/09)



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

Continuing Review (CR): Continuing Review November 2008
Documents Posted:

- 11/13/08: Primary Reviewer 1 Comments
- 11/13/08: 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-ANBL00B1

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/06/07)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/07)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/06/07
- Informed Consent Document for Protocol Version Date 08/06/07
- 02/12/09: Primary Reviewer 1 Comments
- 08/25/08: Study Progress Report

COG-ANBL0421

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/21/07)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/21/07)
- 12/04/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/21/07
- Informed Consent Document for Protocol Version Date 06/21/07
- 02/12/09: Primary Reviewer 1 Comments
- 10/07/08: DSMC Report
- 08/25/08: Study Progress Report

COG-ANHL04B1

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/03/07)



- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/03/07)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/03/07
- Informed Consent Document for Protocol Version Date 08/03/07
- 02/12/09: Primary Reviewer 1 Comments

COG-AOST06P1

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- 01/08/09: Primary Reviewer 1 Comments
- 01/08/09: 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-AREN0532

Continuing Review (CR): Continuing Review August 2008

Documents Posted:

- 08/14/08: Primary Reviewer 1 Comments

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

COG-ASCT0631

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/29/07)
- 02/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/29/07)
- 11/10/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/29/07
- Informed Consent Document for Protocol Version Date 10/29/07 - Assent Consent
- Informed Consent Document for Protocol Version Date 10/29/07 - Donor Consent
- Informed Consent Document for Protocol Version Date 10/29/07 - Recipient Consent
- 01/08/09: Primary Reviewer 1 Comments
- 11/05/08: DSMC Report
- 08/25/08: Study Progress Report



COG-D9902

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/24/08)
- 02/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/24/08)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 07/24/08
- Informed Consent Document for Protocol Version Date 07/24/08
- 08/25/08: Study Progress Report

ECOG-E1301

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/21/03)
- 02/23/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/21/03)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 08/21/03
- Informed Consent Document for Protocol Version Date 08/21/03
- June 2005 - Study Summary
- 11/02/04: ECOG DMC

ECOG-E1302

Continuing Review (CR): Continuing Review February 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/16/08)
- 02/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/16/08)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 04/16/08
- Informed Consent Document for Protocol Version 04/16/08
- October 2008: Study Summary
- Physician Notification Letter

ECOG-E2603

Amendment Review (AR): Addendum #11 (Protocol Version Date 02/03/09)
Documents Posted:

- 02/03/09: ECOG Change Memo (Protocol Version Date 02/03/09)
- CIRB Application (Protocol Version Date 02/03/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/03/09)



- 02/17/09: Acknowledgment of Posting of Addendum #11
- 02/13/09: ECOG Notification of Posting of Addendum #11
- 02/10/09: CIRB Approval Letter (Protocol Version Date 02/03/09) [per Add11]
- 09/29/08: OHRP-IRB Review of Protocol and Informed Consent Changes
- Protocol Version Date 02/03/09
- Informed Consent Document (Protocol Version Date 02/03/09) [per Add11]

ECOG-E2805

Amendment Review (AR): Addendum #5 (Protocol Version Date 01/30/09)

Documents Posted:

- 01/30/09: ECOG Change Memo (Protocol Version Date 01/30/09)
- CIRB Application (Protocol Version Date 01/30/09)
- Summary of CIRB Application Revisions (Protocol Version Date 01/30/09)
- 02/17/09: Acknowledgement of Posting of Addendum #5
- 02/13/09: ECOG Notification of Posting
- 02/06/09: CIRB Approval Letter for Addendum 5 (Protocol Version Date 01/30/09)
- OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol Version Date 01/30/09 [Per Add5]
- Informed Consent Document for Protocol Version Date 01/30/09 [Per Add5]

ECOG-E2905

Amendment Review (AR): Update #1 (Protocol Version Date 01/29/09)

Documents Posted:

- 02/03/09: Change Memo (Protocol Version Date 01/29/09)
- CIRB Application (Protocol Version Date 01/29/09)
- Summary of CIRB Application Revisions (Protocol Version Date 01/29/09)
- 02/11/09: CIRB Update 1 Approval Letter (Protocol Version Date 01/29/09)
- Protocol Version Date 01/29/09
- Informed Consent Document for Protocol Version Date 01/29/09 [per up1]

ECOG-PACCT-1

Amendment Review (AR): Addendum #4 (Protocol Version Date 12/24/08)

Documents Posted:

- 12/24/08: Change Memo (Protocol Version Date 12/24/08)
- CIRB Application (Protocol Version Date 12/24/08)
- Summary of CIRB Application Revisions (Protocol Version Date 12/24/08)
- 01/28/09: CIRB Addendum 4 Approval Letter (Protocol Version Date 12/24/08)
- Protocol Version Date 12/24/08
- Informed Consent Document for Protocol Version Date 12/24/08 [ad4]



- 01/26/09: Primary Reviewer 1 Comments

GOG-0198

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/13/07)
- 02/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 12/13/07)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 12/13/07
- Informed Consent Document for Protocol Version Date 12/13/07
- January 2009: Study Summary

GOG-0204

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/06/06)
- 02/13/09: CIRB Continuing Review Approval Letter February 2009 (Protocol Version Date 09/06/06)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 09/06/06
- 2008 ASCO Abstract

NCCTG-N0147

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/12/08)
- 02/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/12/08)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 08/12/08
- Informed Consent Document for Protocol Version Date 08/12/08 [CR09]
- 10/21/08: DMC AE Report
- October 2008 - Study Summary
- 02/23/09: Primary Reviewer 1 Comments

RTOG-0421

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/14/07)



- 02/18/09: CIRB Continuing Review Approval (Protocol Version Date 02/14/07)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 02/14/07
- 06/19/08: DMC Minutes
- June 2008: Study Progress Report

RTOG-0617

Amendment Review (AR): 12/16/08 Administrative Update (Protocol Version Date 08/29/08)

Documents Posted:

- 12/16/08: Change Memo (Protocol Version Date 08/29/08)
- 02/17/09: CIRB Update Approval Letter (Protocol Version Date 08/29/08)
- Protocol Version Date 08/29/08

SWOG-S0012

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/02/07)
- 02/25/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/02/07)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 02/02/07
- Informed Consent Document for Protocol Version Date 02/02/07
- Study Summary - October 2006

SWOG-S9925

Amendment Review (AR): Revision #12 (Protocol Version Date 01/06/09)

Documents Posted:

- 01/06/09: SWOG Change Memo (Protocol Version Date 01/06/09)
- CIRB Application Protocol Version Date 01/06/09
- Summary of CIRB Application Revisions (Protocol Version Date 01/06/09)
- 02/03/09: CIRB Amendment Revision 12 Approval (Protocol Version Date 01/06/09)
- Protocol Version Date 01/06/09

Serious Adverse Events

Study: ECOG E1105

SAE Posted: 1354425 FU1, 1729567, 267119 FU2, 270229

Study: ECOG E1305



SAE Posted: 1354425 FU1, 267119 FU2, 270229

Study: ECOG E1505

SAE Posted: 1354425 FU1, 1729567, 1809808, 267119 FU2, 270229

Study: NCCTG N0147

SAE Posted: 08-02-15603 FU2

Study: NSABP B-34

SAE Posted: 200812671 SU73 FU2, 200831128 SU113, 200831457 SU114, 200837950 SU111 FU1

Study: NSABP B-38

SAE Posted: FR200802001087 FU2, FR200811005051

Study: NSABP B-40

SAE Posted: FR200802001087 FU2, FR200811005051

Study: NSABP C-08

SAE Posted: 1433885, 1636469 FU1, 1843518 FU2, 1951869

Study: RTOG 0436

SAE Posted: 08-02-15528 FU2, 08-02-15541 FU2

Study: RTOG 0522

SAE Posted: 08-02-15528 FU2, 08-02-15541 FU2

Study: SWOG S0307

SAE Posted: 200714883 SU63, 200715313 SU65 FU2, 200715313 SU65 FU1, 200715679 SU64, 200715690 SU67, 200715690 SU67 FU1, 200716245 SU68, 200718095 SU66, 200810824 SU70, 200811207 SU92, 200811207 SU92 FU1, 200811720 SU71, 200812652 SU72, 200812671 SU73, 200813174 SU74, 200813728 SU75, 200813730 SU76, 200813940 SU77, 200813940 SU77 FU1, 200814162 SU78, 200815097 SU79, 200816063 SU80, 200816075 SU81, 200816114 SU82, 200816114 SU82 FU1, 200816556 SU84, 200816556 SU84 FU1, 200816643 SU83, 200818690 SU90, 200818891 SU89, 200819168 SU91, 200820008 SU85, 200820008 SU85 FU1, 200820008 SU85 FU2, 200821861 SU86, 200821886 SU87, 200822387 SU88, 200822387 SU88 FU1, 200824957 SU98, 200825602 SU94 FU1, 200825602 SU94, 200826944 SU102, 200828012 SU105, 200828012 SU105 FU1, 200828012 SU105 FU2, 200828478 SU95, 200829546 SU97, 200829546 SU97 FU1, 200829635 SU110, 200829635 SU110 FU1, 200831128 SU113, 200831457 SU114, 200831463 SU99, 200831463 SU99 FU1, 200833071 SU100, 200833892 SU101, 200834239 SU103, 200834239 SU103 FU1, 200835032 SU104, 200835467 SU106, 200835467 SU106 FU1, 200836245 SU108, 200836438 SU109, 200837950 SU111, 200837950 SU111 FU1, 200838304 SU112, 200839971 SU115, 200839971 SU115 FU1, AU-2007-



034510 SU54, AU-2007-042893 SU62, FR-2007-034745 SU56, FR-2007-040962
SU59, FR-2007-041732 SU61, FR-2007-041732 SU61 FU1, GB-2007-028574
SU55, GB-2007-040750 SU60, LT-2007-038758 SU57, US-2007-038539 SU58

Corrections to Previous Study Activity Updates

NCCTG-N0434 (MA.27D)

Continuing Review Approval January 2009

Documents Posted:

CIRB Continuing Review Application (Protocol Version Date 07/03/07)

01/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date
07/03/07)

12/03/08: CIRB Continuing Review Reminder Notice

Protocol Version Date 07/03/07

Correction:

The Continuing Review for this study was inadvertently left off the Study Activity
update in January.

If you have any questions about your local review process, please contact your
Local IRB office.

If you have any questions about the CIRB Initiative, please contact the CIRB at
ncicirbcontact@emmes.com.