



NCI Central IRB Study Activity Update

March 31, 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.

Adult CIRB Studies

CALGB-30506

Initial Review 2009 Approval
Documents Posted:

- Protocol Version Date 02/03/09
- Protocol Version Date 12/11/08
- Appendix C: Specimen Banking Policies & Guide to Access to CALGB Specimens
- Informed Consent Document for Protocol Version Date 02/03/09
- CIRB Application (Protocol Version Date 02/03/09)
- CIRB Application (Protocol Version Date 12/11/08)
- 01/09/09: Primary Reviewer 1 Comments
- 01/09/09: Primary Reviewer 2 Comments
- 01/09/09: Primary Reviewer 4 Comments
- 02/09/09: CIRB Final Approval Letter (Protocol Version Date 02/03/09)
- 02/03/09: Group Response Letter
- 01/16/09: CIRB Approval Pending Modification of Initial Review
- 01/09/09: Minutes - Initial Review
- CALGB Concerns about Recurrence in Lung Cancer Patients Form
- CALGB EQ-5D Form
- CALGB LC13 Form
- CALGB Quality of Life Questionnaire
- CALGB Smoking Status Questionnaire

Pediatric CIRB Studies

COG-AALL07P1

Initial Review 2009 Approval
Documents Posted:

- Protocol Version Date 02/09/09
- Protocol Version Date 02/09/09 - Highlighted Changes
- Protocol Version Date 11/10/08
- Protocol Version Date 11/10/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/09/09



- CIRB Application (Protocol Version Date 02/09/09)
- CIRB Application (Protocol Version Date 11/10/08)
- 12/11/08: Primary Reviewer 1 Comments
- 12/11/08: Primary Reviewer 2 Comments
- 12/11/08: Primary Reviewer 3 Comments
- 12/11/08: Pharmacist Reviewer Comments
- 03/20/09: CIRB Acknowledgement of COG AALL07P1 Activation Memo
- 02/27/09: CIRB Final Approval Letter (Protocol Version Date 02/09/09)
- 02/09/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/10/08)
- 12/18/08: CIRB Approval Pending Modification of Initial Review Letter (Protocol Version Date 11/10/08)
- 12/11/08: Minutes - Initial Review

Other Activity Posted:

CALGB-80101

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/22/07)
- 03/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/22/07)
- 03/19/09: CIRB Approval of Group Response to Continuing Review
- 03/17/09: CALGB Response to CIRB
- 02/05/09: CIRB Continuing Review Approval Pending Modifications (Protocol Version 01/22/07)
- 12/03/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/22/07
- Informed Consent Document for Protocol Version Date 01/22/07 [CR09]
- 01/26/09: Primary Reviewer 1 Comments
- 01/26/09: Minutes - Continuing Review
- 11/14/08: DSMB Report
- November 2008 - Study Summary

CALGB-80303

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/17/07)
- 03/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/17/07)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 08/17/07



- Informed Consent Document for Protocol Version Date 08/17/07
- 03/16/09: Primary Reviewer 1 Comments
- ASCO#4508 Pancreatic Cancer (2007 ASCO Annual Meeting)
- ASCO#4524 Pancreatic Cancer (2007 ASCO Annual Meeting)
- ASCO#9008 Quality of Life Management (2007 ASCO Annual Meeting)
- June 2007 - Study Summary
- 06/16/06 DSMB Statements

CALGB-90104

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/26/07)
- 03/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 03/26/07
- Informed Consent Document for Protocol Version Date 03/26/07
- Study Summary - June 2006
- DSMB Report October 14, 2005

CALGB-90202

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/15/07)
- 03/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/15/07)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 11/15/07
- Informed Consent Document for Protocol Version Date 11/15/07 [CR09]
- 03/16/09: Primary Reviewer 1 Comments
- 11/14/08: DSMB Report
- November 2008 - Study Summary

CALGB-90401

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/19/07)
- 03/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/19/07)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 09/19/07
- Informed Consent Document for Protocol Version Date 09/19/07



- 03/16/09: Primary Reviewer 1 Comments
- 11/14/08: DSMB Report
- November 2008 - Study Summary

COG-AALL03B1

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

- 02/12/09: 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-AALL0331

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

- 02/12/09: 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-AALL05B1

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

- 02/12/09: 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-ADVL0524

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

- CIRB Application (Protocol Version Date 10/01/07)
- 03/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/01/07)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 10/01/07
- Informed Consent Document for Protocol Version Date 10/01/07
- Spring 2009 Study Progress Report
- 11/06/08: DSMC Report



COG-ADVL0525

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- 02/12/09: 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-ANBL00B1

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- 02/12/09: 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-ANBL0421

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- 02/12/09: 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-ANHL04B1

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- 02/12/09: 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-ASCT0631

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- 02/12/09: 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-D9902

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

- 02/12/09: Minutes - Continuing Review

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

ECOG-E2100

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

- CIRB Continuing Review Application (Protocol Version Date 05/30/07)
- 03/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/30/07)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 05/30/07
- Informed Consent Document for Protocol Version Date 05/30/07
- 03/16/08: Primary Reviewer 1 Comments
- 10/01/08 Journal of Clinical Oncology (Schneider et al.)
- October-November 2008 DMC Recommendations

ECOG-E2805

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

- CIRB Continuing Review Application (Protocol Version Date 01/30/09)
- 03/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/30/09)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 01/30/09
- Informed Consent Document for Protocol Version Date 01/30/09 [CR09]
- November 2008 - Study Summary
- October-November 2008 - DMC Recommendations

ECOG-E3805

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

- CIRB Continuing Review Application (Protocol Version Date 10/01/08)
- 03/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/01/08)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 10/01/08



- Informed Consent Document for Protocol Version Date 10/01/08 [CR09]
- December 20, 2008 Journal of Clinical Oncology (Millikan)
- November 2008 - Study Summary
- October-November 2008 - DMC Recommendations

ECOG-E4402

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

- CIRB Continuing Review Application (Protocol Version Date 04/17/08)
- 03/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/17/08)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 04/17/08
- Informed Consent Document for Protocol Version Date 4/17/08
- 03/16/09: Primary Reviewer 1 Comments
- ECOG Preliminary Pharmacokinetic (PK) Analysis
- November 2008 - Study Summary
- October-November 2008 DMC Recommendations

ECOG-PACCT-1

Amendment Review (AR): Update 4 Approval March 2009
Documents Posted:

- 03/18/09: ECOG Change Memo (Protocol Version Date 03/18/09)
- 03/18/09: CIRB Update 4 Approval Letter (Protocol Version Date 03/18/09)
- Protocol Version Date 03/18/09
- Informed Consent Document for Protocol Version Date 03/18/09 [up4]

GOG-0218

Amendment Review (AR): Revision 5 Approval February 2009
Documents Posted:

- 02/27/09: GOG Change Memo (Protocol Version Date 02/27/09)
- 12/30/08: GOG Change Memo (Protocol Version Date 12/30/08)
- CIRB Application (Protocol Version Date 02/27/09)
- CIRB Application (Protocol Version Date 12/30/08)
- Summary of CIRB Application Revisions (Protocol Version Date 12/30/08)
- 03/02/09: CIRB Revision 5 Approval Letter (Protocol Version Date 02/27/09)
- 02/20/09: CIRB Revision 5 Approval Pending Modifications (Protocol Version Date 12/30/08)
- Protocol Version Date 02/27/09
- Protocol Version Date 12/30/08
- Appendix I



- Appendix II
- Appendix III
- Appendix IV
- Appendix V
- Appendix VI
- Appendix VII
- Appendix VIII
- Informed Consent Document for Protocol Version Date 02/27/09 [Rev5]
- 02/06/09: Minutes - Revision 5

NCIC CTG-BR.19

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/03/05)
- 03/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/03/05)
- 03/03/09: Continuing Review Reminder Notice
- Protocol Version Date 01/03/05
- Informed Consent Document for Protocol Version Date 01/03/05
- 02/25/08: Report of Studies

NCIC CTG-MA.27B

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/22/07)
- 03/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 5/22/07)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 05/22/07
- 03/16/09: Primary Reviewer 1 Comments
- Informed Consent Document for Protocol Version Date 05/22/07
- Spring 2008 - Study Summary

NSABP-C-09

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/14/07)
- 03/23/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/14/07)
- 03/13/09: NSABP Cover Memo
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 06/14/07



- Informed Consent Document for Protocol Version Date 06/14/07

RTOG-0129

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/06/08)
- 03/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/08)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 08/06/08
- Informed Consent Document for Protocol Version Date 08/06/08 [Per CR Mar 2009]
- 01/09/09: DMC Minutes
- Study Summary - January 2009
- ASTRO - Abstract

RTOG-0436

Recruitment Material - Patient Brochure

Documents Posted:

- 03/23/09: CIRB Approval Letter Patient Brochure
- 03/09/09: CIRB Approval Pending Modification - Recruitment Materials
- Patient Brochure
- 02/23/09: Primary Reviewer 1 Comments

SWOG-S0502

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/24/09)
- 03/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/24/09)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 04/24/09
- Informed Consent Document for Protocol Version Date 04/24/08 [CR09]
- Informed Consent Document for Protocol Version Date 04/24/08: Tissue
- 03/16/09: Primary Reviewer 1 Comments
- 10/31/08: DSMC Minutes



Serious Adverse Events

Study: ECOG E2100

SAE Posted: 1118620 FU1, 1354425 FU1, 1433885, 1729567, 1803957 FU1, 1809808, 267119 FU2, 270229

Study: ECOG E4599

SAE Posted: 1118620 FU1, 1354425 FU1, 1433885, 1729567, 1803957 FU1, 1809808, 267119 FU2, 270229

Study: ECOG E5103

SAE Posted: 1118620 FU1, 1324148, 1354425 FU1, 1433885, 1475911, 1580693, 1636469 FU1, 1729567, 1729567 FU1, 1803957 FU1, 1809808, 1843518 FU2, 267119 FU2, 270229

Study: GOG 0218

SAE Posted: 1118620 FU1, 1205368, 1205368 FU1, 1324148, 1354425 FU1, 1433885, 1477246, 1477246 FU1, 1580693, 1729567, 1729567FU1, 1803957, 1803957 FU1, 1809808, 1809808 FU1, 1843518 FU2, 1859262 FU1, 1881593, 1951869, 267119 FU2, 270229, 556768 FU1

Study: NSABP B-38

SAE Posted: JP200812000002

Study: NSABP B-40

SAE Posted: JP200812000002

Study: RTOG 0436

SAE Posted: 08-02-14699 FU2, 08-02-15750, 08-02-15831

Study: RTOG 0522

SAE Posted: 08-02-14699 FU2, 08-02-15750, 08-02-15831

Study: SWOG S0307

SAE Posted: 200711360 SU69, 200711360 SU69 FU2, 200810824 SU70 FU1, 200812671 SU73 FU1, 200812671 SU73 FU2, 200823590 SU96, 200823590 SU96 FU1, 200824407 SU93, 200824407 SU93 FU1, 200824407 SU93 FU2, 200828565 SU107, TR-2007-006800 SU44 FU1



Corrections to Previous Study Activity Updates

SWOG-S9910

Continuing Review (CR) March 2009 Approval
Documents Posted:

Informed Consent Document (Instructions for Local Institutions) for Protocol
Version Date 11/29/07

Informed Consent Document for Protocol Version Date 11/29/07 [CR09]

Correction:

Informed Consent Documents were not included in the posting of the Continuing
Review for the March 2009 approval of this action.

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.