



NCI Central IRB Study Activity Update

July 15, 2008

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-AALL0622

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 03/28/08
- Protocol Version Date 03/28/08 - Highlighted Changes
- Protocol Version Date 10/08/07
- Protocol Version Date 10/08/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 03/28/08
- CIRB Application (Protocol Version Date 03/28/08)
- CIRB Application (Protocol Version Date 10/08/07)
- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Primary Reviewer 2 Comments
- 01/10/08: Primary Reviewer 3 Comments
- 01/10/08: Pharmacist Comments
- 05/28/08: CIRB Final Approval Letter (Protocol Version Date 03/28/08)
- 03/28/08: COG Response to Approval Pending Modification (Protocol Version Date 10/08/07)
- 01/25/08: CIRB Approval Pending Modification (Protocol Version Date 10/08/07)
- 01/10/08: Minutes - Initial Review

Other Activity Posted:

CALGB-90203

Recruitment Materials Approval May 2008
Documents Posted:

- 05/07/08: CIRB Recruitment Materials Approval Letter
- 04/04/08: CALGB Response to CIRB
- 03/07/08: CIRB Approval Pending Modification - Patient Recruitment Materials
- Recruitment Brochure



- CD Study Summary
- 02/22/08: Primary Reviewer 1 Comments
- 02/22/08: Primary Reviewer 2 Comments
- 04/21/08: Minutes - Group Response to Patient Recruitment Materials

CALGB-90401

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/19/07)
- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/19/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 09/19/07
- Study Summary - December 2007

COG-AALL0331

Amendment Review (AR): Review of AALL0331 Family/Patient Letter regarding Temporary Study Enrollment Suspension

Documents Posted:

- 07/01/08: CIRB Approval of the AALL0331 Family/Patient Study Suspension Letter
- 06/19/08: COG Response to PedCIRB APM outcome Family/Patient Study Suspension Letter
- 06/19/08: Patient/Family Letter
- 06/10/08: CIRB Approval Pending Modification Family/Patient Study Suspension Letter (Protocol Version Date 09/25/06)

COG-AALL0433

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/23/07)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/23/07)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/23/07
- Informed Consent Document for Protocol Version Date 02/23/07
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report



COG-AALL0434

Amendment Review (AR): Review of AALL0434 Family/Patient Letter regarding Temporary Study Enrollment Suspension
Documents Posted:

- 07/01/08: CIRB Approval of the AALL0434 Family/Patient Study Suspension Letter
- 06/16/08: COG Response to PedCIRB APM outcome Family/Patient Study Suspension Letter
- 06/16/08: Patient/Family Letter
- 06/10/08: CIRB Approval Pending Modification Family/Patient Study Suspension Letter (Protocol Version Date 08/03/07)

COG-AAML0523

Amendment Review (AR): AAML0523 Amendment #1 (Protocol Version Date 05/06/08)
Documents Posted:

- CIRB Application (Protocol Version Date 05/06/08)
- CIRB Application (Protocol Version Date 02/22/08)
- 06/27/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 05/06/08)
- 05/06/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/06/08)
- 05/02/08: Approval Pending Modification Letter (Protocol Version Date 02/22/08)
- 02/22/08: Change Memo (Protocol Version Date 02/22/08)
- Protocol Version Date 05/06/08
- Protocol Version Date 05/06/08 - Highlighted Changes
- Protocol Version Date 02/22/08
- Protocol Version Date 02/22/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 05/06/08
- 04/10/08: Primary Reviewer 1 Comments
- 04/10/08: Minutes - Amendment Review

COG-AAML0531

Continuing Review (CR): June 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/13/08)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/13/08)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version 03/13/08



- Informed Consent Document for Protocol Version Date 03/13/08
- Informed Consent Document for Protocol Version Date 03/13/08 - Additional Bone Marrow
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

COG-ACCL0631

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/07/08)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/07/08)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/07/08
- Informed Consent Document for Protocol Version Date 02/07/08

COG-ACNS0221

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/15/05)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/15/05)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/15/05
- Informed Consent Document for Protocol Version Date 11/15/05
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

COG-ACNS0334

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/15/07)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/15/07)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/15/07
- Informed Consent Document for Protocol Version Date 06/15/07
- 02/04/08: Study Progress Report



COG-ADVL0524

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/01/07)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/01/07)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/01/07
- Informed Consent Document for Protocol Version Date 10/01/07
- 02/04/08: Study Progress Report

COG-ADVL0525

Amendment Review (AR): Amendment #2 (Protocol Version 05/07/08)

Documents Posted:

- CIRB Application (Protocol Version Date 05/07/08)
- 06/30/08: CIRB Amendment #2 Approval Letter (Protocol Version Date 05/07/08)
- 05/07/08: Change Memo (Protocol Version Date 05/07/08)
- Protocol Version Date 05/07/08
- Protocol Version Date 05/07/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 05/07/08

COG-AEWS0521

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/31/08)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/31/08)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/31/08
- Informed Consent Document for Protocol Version Date 01/31/08 - Part I - Feasibility
- Informed Consent Document for Protocol Version Date 01/31/08 - Part II - Randomized Study

COG-AEWS07P1

Continuing Review (CR) June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/12/07)



- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/12/07)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/12/07
- Informed Consent Document for Protocol Version Date 10/12/07

COG-AHOD03P1

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/08/05)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 12/08/05)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 12/08/05
- Informed Consent Document for Protocol Version Date 12/08/05
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

COG-AHOD0431

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/11/07)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/11/07)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/11/07
- Informed Consent Document for Protocol Version 05/11/07: Initial Treatment
- Informed Consent Document for Protocol Version 05/11/07: Relapse Treatment
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

COG-ARET0331

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/14/07)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/14/07)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/14/07



- Informed Consent Document for Protocol Version Date 09/14/07
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

COG-ARST0531

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/16/06)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/16/06)
- 04/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/16/06
- Informed Consent Document for Protocol Version 10/16/06
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

ECOG-E1A05

Amendment Review (AR): Addendum #1 Approval Protocol Version Date 04/25/08

Documents Posted:

- 04/25/08: Change Memo (Protocol Version Date 04/25/08)
- CIRB Application (Protocol Version Date 01/23/08)
- Summary of CIRB Application Revisions (Protocol Version Date 01/23/08)
- CIRB Application (Protocol Version Date 06/25/07)
- 06/11/08: CIRB Addendum #1 Approval Letter (Protocol Version Date 04/25/08)
- 05/09/08: ECOG Response to CIRB request to modify Consent
- 04/02/08: CIRB Approval Pending Modification (Protocol Version Date 01/23/08)
- Quality of Life Assessment Form
- Protocol Version Date 04/25/08
- Protocol Version Date 01/23/08
- Protocol Version Date 06/25/07
- Informed Consent Document for Protocol Version Date 04/25/08 [Per Add #1]
- 03/07/08: Primary Reviewer 1 Comments
- 03/17/08: Minutes - Addendum #1 Review
- 03/07/08: Minutes - Addendum #1 Review



ECOG-E2603

Amendment Review (AR): Addendum #10 Approval Protocol Version

Date 04/03/08

Documents Posted:

- 04/03/08: Change Memo (Protocol Version Date 04/03/08)
- CIRB Application (Protocol Version Date 04/03/08)
- Summary of CIRB Application Changes (Protocol Version Date 04/03/08)
- 05/27/08: CIRB Addendum 10 Approval Letter (Protocol Version Date 04/03/08)
- Protocol Version Date 04/03/08
- 05/02/08: Primary Reviewer 1 Comments
- 05/02/08: Minutes - Addendum 10 Review

ECOG-E2805

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/21/07)
- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/21/07)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 03/21/07
- Informed Consent Document for Protocol Version Date 03/21/07 [Per Jun08 CR]
- Study Summary - November 2007
- 09/24/07: DMC Recommendations

ECOG-E5202

Amendment Review (AR): Update #3 Approval Protocol Version Date 05/14/08

Documents Posted:

- 05/14/08: Change Memo (Protocol Version Date 05/14/08)
- CIRB Application (Protocol Version Date 05/14/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/14/08)
- 06/25/08: CIRB Update 3 Approval Letter (Protocol Version Date 05/14/08)
- Protocol Version Date 05/14/08
- Informed Consent Document for Protocol Version Date 05/14/08 [Per Up3]



NCIC CTG-27B

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/22/07)
- 06/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/22/07)
- 05/09/08: NCIC CTG Closure to Accrual Memo
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 05/22/07
- Informed Consent Document for Protocol Version Date 05/22/07 [Per Jun08 CR]
- 10/20/07: DSMC Summary Report
- Study Summary

NSABP-C-09

Continuing Review (CR): June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/14/07)
- 06/25/08: CIRB Continuing Review Approval Letter (Protocol Version 06/14/07)
- 05/23/08: NSABP Cover Letter
- 05/09/08: Continuing Review Reminder Notice
- 10/23/07: NSABP Instructions following Closure for Institutions that have not enrolled Patients
- 10/23/07: NSABP Instructions following Closure for Institutions that have enrolled Patients
- Protocol Version Date 06/14/07
- 06/16/08: Primary Reviewer 1 Comments
- 10/12/07: DMC Minutes
- Study Summary
- Dear Patient Closure Letter

SWOG-S0303

****ADMINISTRATIVELY COMPLETED as of 1/1/07****

Continuing Review (CR): Protocol Version Date 07/12/05

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/12/05)
- 07/03/08: CIRB Acknowledgement of Administrative Closure



- 06/09/08: Continuing Review Reminder Notice
- Protocol Version Date 07/12/05

SWOG-S0777

****Study is Re-Activated and open to enrollment as of July 1, 2008****

Amendment Review (AR): Re-Activation Revision Approval Protocol Version
Date 05/30/08

Documents Posted:

- 05/30/08: Change Memo (Protocol Version Date 05/30/08)
- CIRB Application (Protocol Version Date 05/30/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/30/08)
- 07/02/08: CIRB Acknowledgement of Re-Activation (Protocol Version Date 05/30/08)
- 06/25/08: CIRB Re-Activation Revision Approval Letter (Protocol Version Date 05/30/08)
- 06/09/08: CTEP - PIO Clarification Letter
- Protocol Version Date 05/30/08
- Informed Consent Document for Protocol Version Date 05/30/08 [Per Re-Act Rev]

Serious Adverse Events

**Study: ACOSOG Z1031
SAE Posted: 1136287 FU1**

**Study: CALGB 30607
SAE Posted: 1340420, 1010206**

**Study: CALGB 80203
SAE Posted: 08-02-14293, 06-02-08451 / DDL 217**

**Study: CALGB 40503
SAE Posted: 1230483 FU1**

**Study: CALGB 80303
SAE Posted: 1230483 FU1**

**Study: CALGB 90206
SAE Posted: 1230483 FU1**

**Study: CALGB 90401
SAE Posted: 1230483 FU1**



Study: CALGB SWOG 80405
SAE Posted: 08-02-14293, 06-02-08451 / DDL 217

Study: ECOG E1105
SAE Posted: 1230483 FU1

Study: ECOG E1305
SAE Posted: 1230483 FU1

Study: ECOG E1505
SAE Posted: 1230483 FU1

Study: ECOG E2100
SAE Posted: 1230483 FU1

Study: ECOG E2805
SAE Posted: 1340420, 1010206, 1031556, 1853625

Study: ECOG E2603
SAE Posted: 1853625

Study: ECOG E4599
SAE Posted: 1230483 FU1

Study: ECOG E5103
SAE Posted: 1230483 FU1

Study: ECOG E5202
SAE Posted: 1230483 FU1

Study: ECOG E5204
SAE Posted: 1230483 FU1

Study: GOG 0213
SAE Posted: 1230483 FU1, 240959 FU1

Study: GOG 0218
SAE Posted: 1230483 FU1

Study: NSABP B-38
SAE Posted: US200803001632, US200803001632 FU2, DE200805000250

Study: NSABP B-40
SAE Posted: 1230483 FU1, US200803001632 FU2, DE200805000250



Study: NSABP C-08
SAE Posted: 1230483 FU1, 253571 FU1

Study: RTOG 0320
SAE Posted: 2007SP018230 FU5

Study: RTOG 0436
SAE Posted: 08-02-14293

Study: RTOG 0522
SAE Posted: 08-02-14293

Study: RTOG 0525
SAE Posted: 2007SP018230 FU5

Study: SWOG 0600
SAE Posted: 08-02-14293, 1230483 FU1

Study: SWOG S0502
SAE Posted: 1230483 FU1

Study: SWOG S0518
SAE Posted: 1230483 FU1

Study: NCCTG N0147
SAE Posted: 08-02-14293

Corrections to Previous Study Activity Updates

COG-AALL0622

Initial Review 2008 Approval
Documents Posted:

Correction:

COG-AALL0622 was mistakenly added to the June 30th Study Activity Update.
The AALL0622 study activation was postponed by COG until July.

ECOG-PACCT-1

Continuing Review (CR): June 2008 Approval
Documents Posted:

Informed Consent Document for Protocol Version Date 03/21/08 (Per Jun08 CR)



Correction:
Existing consent was replaced with updated version to correct missing last page.

SWOG-S0421

Continuing Review (CR): November 2007 Approval
Documents Posted:

Informed Consent Document for Protocol Version Date 02/01/07 [Per Nov 07 CR]

Correction:
Existing consent was replaced with updated version to correct formatting error.

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.