



NCI Central IRB Study Activity Update

January 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.

Pediatric CIRB Studies

COG-ADVL0821

Initial Review December 2008 Approval
Documents Posted:

- Protocol Version Date 12/24/08
- Protocol Version Date 12/24/08 - Highlighted Changes
- Protocol Version Date 11/04/08
- Protocol Version Date 11/04/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 12/24/08
- CIRB Application (Protocol Version Date 12/24/08)
- CIRB Application (Protocol Version Date 11/04/08)
- 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
- 01/26/09: COG Activation Memo
- 01/23/09: CIRB Acknowledgement of COG ADVL0821 Activation Memo
- 01/06/09: CIRB Approval Letter (Protocol Version Date 12/24/08)
- 12/24/08: COG Group Response to Approval Pending Modification Letter (Protocol Version Date 12/24/08)
- 12/18/08: CIRB Approval Pending Modification of Initial Review Letter (Protocol Version Date 11/04/08)
- 12/11/08: Minutes - Initial Review

Other Activity Posted:

ACOSOG-Z6051

Amendment Review (AR): Participant Recruitment Brochure
Documents Posted:

- 01/14/09: Recruitment Brochure Approval Letter
- Recruitment Brochure
- Primary Reviewer 1 Comments



CALGB-10501

Continuing Review (CR) Approval December 2008

Documents Posted:

- 12/05/08: Minutes - Continuing Review

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

CALGB-10603

Continuing Review (CR) Approval December 2008

Documents Posted:

- 12/05/08: Minutes - Continuing Review

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

CALGB-30610

Continuing Review (CR) Approval December 2008

Documents Posted:

- 12/05/08: Minutes - Continuing Review

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

CALGB-30610

Amendment Review (AR) Update #1 (Protocol Version Date 10/28/08)

Documents Posted:

- 12/05/08: Minutes – Update #1 Review

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

COG-AALL0331

Amendment Review (AR): **CIRB Acknowledgement of Typographical Errors in Therapy Delivery Maps**

Documents Posted:

- 01/14/09: CIRB Acknowledgement - Typographical Errors in the Therapy Delivery Map
- 12/24/08: COG Memo - Notification of Typographical Errors in the Therapy Delivery Maps



COG-AALL03N1

Continuing Review (CR): Continuing Review July 2008

Documents Posted:

- 07/10/08: Primary Reviewer 1 Comments
- 07/10/08: 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-AALL0433

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-AALL0434

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: Minutes - Continuing Review

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

Amendment Review (AR): Amendment #2B (Protocol Version Date 08/07/08) and Reactivation

Documents Posted:

- 07/10/08: Primary Reviewer 1 Comments
- 07/10/08: 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

Amendment Review (AR): **Acknowledgement of COG AALL07P4 - Notification of Error in the Consolidation TDM**

Documents Posted:

- 01/16/09: CIRB Acknowledgement Memo – Notification of Error in the Consolidation TDM
- 01/16/09: COG Memo - Notification of Error in the Consolidation TDM

COG-AAML0431

Amendment Review (AR): **NCI Information Sheet Re Use of Banked Tissue for Research**

Documents Posted:

- 01/14/09: CIRB Acknowledgement Memo - Update NCI Information Sheet Re Use of Banked Tissue for Research
- 12/12/08: COG Update Memo - NCI Information Sheet Re Use of Banked Tissue for Research

COG-AAML0531

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ABTR04B1

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ACCL04C2

****Closed to Accrual by COG - Effective January 16, 2009****

Amendment Review (AR): **Acknowledgement of ACCL04C2 Study Closure (01/16/09)**

Documents Posted:

- 01/16/09: CIRB Acknowledgement of COG ACCL04C2 Closure to Accrual Memo
- 01/16/09: COG Closure of ACCL04C2 Memo

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ACCRN07

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ACCL05C1

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

Documents Posted:

- CIRB Application (Protocol Version Date 10/31/08)
- 01/16/09: CIRB Acknowledgement of COG ACCL05C1 Amendment #2A
- 12/19/08: CIRB Approval Pending Modification Letter (Protocol Version Date 10/31/08)
- 10/31/08: COG Change Memo (Protocol Version Date 10/31/08)
- Protocol Version Date 10/31/08
- Protocol Version Date 10/31/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 10/31/08



COG-ACNS0221

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ACNS0232

Continuing Review (CR): Continuing Review December 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/09/08)
- 01/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/09/08)
- 01/02/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/09/08)
- 12/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/09/08)
- 11/11/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/09/08
- Informed Consent Document for Protocol Version Date 06/09/08
- 08/25/08: Study Progress Report
- 04/11/08: DSMC Report

COG-ACNS0334

Amendment Review (AR): **NCI Information Sheet Re Use of Banked Tissue for Research**

Documents Posted:

- 01/14/09: CIRB Acknowledgement Memo - Update NCI Information Sheet Re Use of Banked Tissue for Research
- 12/12/08: COG Update Memo - NCI Information Sheet Re Use of Banked Tissue for Research

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-AEWS0521

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-AEWS07P1

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-AGCT0521

Continuing Review (CR): Continuing Review July 2008

Documents Posted:

- 07/10/08: Primary Reviewer 1 Comments
- 07/10/08: 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

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-AHOD0431

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ANBL00P3

Continuing Review (CR): Continuing Review July 2008

Documents Posted:

- 07/10/08: Primary Reviewer 1 Comments
- 07/10/08: 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-AOST06B1

Continuing Review (CR): Continuing Review July 2008

Documents Posted:

- 07/10/08: Primary Reviewer 1 Comments
- 07/10/08: 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-AOST06P1

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/01/08)
- 01/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/01/08)
- 12/04/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 07/01/08
- Informed Consent Document for Protocol Version Date 07/01/08
- 11/06/08: DSMC Report



COG-ARAR0331

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-AREN0321

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ARET0331

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ARET0332

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: 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-ARST0332

Continuing Review (CR): Continuing Review July 2008

Documents Posted:

- 07/10/08: Primary Reviewer 1 Comments
- 07/10/08: 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-ARST03P1

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/12/06)
- 01/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/12/06)
- 11/11/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/12/06
- Protocol Version Date 01/12/06 - Highlighted Changes

COG-ARST0531

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: Minutes - Continuing Review

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

ECOG-E1302

Amendment Review (AR) Closed to Accrual-Effective November 13, 2008

Documents Posted:

- 12/05/08: Minutes – Closure Material

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

ECOG-E1900

Amendment Review (AR) Closed to Accrual-as of November 17, 2008

Documents Posted:

- 12/05/08: Minutes – Closure Materials



- 12/05/08: Primary Reviewer 1 Comments

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

ECOG-E2603

Continuing Review (CR) Approval January 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/09/08)
- 01/28/09: CIRB Continuing Review Approval (Protocol Version Date 07/09/08)
- 12/03/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 07/09/08
- 01/26/09: Primary Reviewer 1 Comments
- November 2008 - Study Summary
- 10/29/08 - 11/04/08: DMC Recommendations

ECOG-E5103

Continuing Review (CR) Approval December 2008
Documents Posted:

- 12/05/08: Minutes - Continuing Review

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

ECOG-E5204

Continuing Review (CR) Approval January 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/26/08)
- 01/27/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/26/08)
- 12/03/08: CIRB Continuing Review Reminder Notice
- 11/24/08: Protocol Notice: Shortage of Leucovorin
- Protocol Version Date 11/26/08
- Informed Consent Document for Protocol Version Date 11/26/08 [CR09]
- 01/09/09: Primary Reviewer 1 Comments
- November 2008 - Study Summary
- 10/29/08-11/04/08 DMC Recommendations

SWOG-S0307

Continuing Review (CR) Approval January 2009



Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/25/08)
- 01/28/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/25/08)
- 12/03/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 07/25/08
- Informed Consent Document for Protocol Version Date 07/25/08 [CR09]
- Informed Consent Document for Protocol Version Date 07/25/08: Notes for Local Institutions
- 01/26/09: Primary Reviewer 1 Comments
- 01/05/09: SAE Report
- 10/31/08: DSMC Minutes
- October 30 - November 2, 2008 - Study Summary

Serious Adverse Events

Study: CALGB 30607
SAE Posted: 1460979 FU2

Study: CALGB 40502
SAE Posted: 1940244 Fu1

Study: CALGB 40503
SAE Posted: 1187600 FU1, 1226348 FU1, 1466045, 1466045 FU1, 1506455, 263899 FU1

Study: CALGB 80203
SAE Posted: 07-02-12323 FU1, 07-02-12741, 08-02-14619, 08-02-14660 FU2, 08-02-15006

Study: CALGB 80303
SAE Posted: 1187600 FU1, 1226348 FU1, 1466045, 1466045 FU1, 1506455, 263899 FU1

Study: CALGB 90206
SAE Posted: 1187600 FU1, 1226348 FU1, 1466045, 1466045 FU1, 1506455, 263899 FU1

Study: CALGB 90401
SAE Posted: 1187600 FU1, 1226348 FU1, 1466045, 1466045 FU1, 1506455, 263899 FU1

Study: CALGB ECOG-100104
SAE Posted: 1358268, 1779801



Study: CALGB SWOG C80405

SAE Posted: 07-02-12323 FU1, 08-02-15006, 1226348 FU1, 1466045, 1466045 FU1, 1506455

Study: GOG 0213

SAE Posted: 1187600 FU1, 1354425, 1466045, 1466045 FU1, 1506455, 1506455 FU1, 1636469, 1653936 FU2, 1820686 FU1, 1843518, 1859262, 253621, 257028 FU2

Study: GOG 0218

SAE Posted: 1187600 FU1, 1466045, 1466045 FU1, 1506455, 1506455 FU1, 1636469, 1653936 FU2, 1820686 FU1, 1843518, 1859262, 253621, 257028 FU2

Study: NCCTG N0147

SAE Posted: 08-02-14028 FU1

Study: NSABP B-34

SAE Posted: 200828012 SU105, 200828012 SU105 FU1, 200834239 SU103, 200834239 SU103 FU1, 200835032 SU104

Study: NSABP B-38

SAE Posted: DE200809006185, PT200808000032

Study: NSABP B-40

SAE Posted: 258964 FU1, 263520 FU3, 266802 FU2, 267119 FU2, 268357, 268723, 269963, DE200809006185, PT200808000032

Study: NSABP C-08

SAE Posted: 1354425, 1506455 FU1, 268723

Study: RTOG 0436

SAE Posted: 08-02-14861 FU1, 08-02-15006 FU2, 08-02-15290, 08-02-15301

Study: RTOG 0522

SAE Posted: 08-02-14861 FU1, 08-02-15006 FU2, 08-02-15290, 08-02-15301

Study: RTOG 0525

SAE Posted: 2008SP001728 FU2, 2008SP003086 FU1, 2008SP006508 FU1, 2008SP009306 FU1, 2008SP010385 FU1, 2007SP007552 FU9, 2007SP018230 FU7

Study: SWOG S0502

SAE Posted: 1187600 Fu1, 1226348 FU1, 1466045, 1466045 FU1, 1477246, 1506455, 1506455 Fu1, 1636469, 1820686 FU1, 1843518, 1859262, 257028 FU2, 260365 FU1, 263899 FU1, 265261, 265652, 267119 FU2, 556768 FU1



Study: SWOG S0518
SAE Posted: 1477246, 1506455, 1506455 FU1, 1859262, 265261, 265652,
267119 FU2, 556768 FU1

Study: SWOG S0600
SAE Posted: 07-02-12741, 08-02-14619, 265261, 265652

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.