



NCI Central IRB Study Activity Update December 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.

Adult CIRB Studies

CALGB-40601

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 09/29/08
- Protocol Version Date 08/26/08
- Protocol Version Date 06/23/08
- Protocol Version Date 02/07/08
- Protocol Version Date 09/24/07
- Informed Consent Document for Protocol Version Date 09/29/08
- CIRB Application (Protocol Version Date 09/29/08)
- Summary of CIRB Application Revisions (Protocol Version Date 09/29/08)
- CIRB Application (Protocol Version Date 08/26/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/26/08)
- CIRB Application (Protocol Version Date 06/23/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/23/08)
- CIRB Application (Protocol Version Date 02/07/08)
- CIRB Application (Protocol Version Date 09/24/07)
- 11/07/08: Primary Reviewer 1 Comments
- 03/17/08: Primary Reviewer 1 Comments
- 03/17/08: Primary Reviewer 2 Comments
- 03/17/08: Primary Reviewer 4 Comments
- 12/07/07: Primary Reviewer 1 Comments
- 12/07/07: Primary Reviewer 4 Comments
- 11/26/07: Primary Reviewer 2 Comments
- 11/26/07: Primary Reviewer 4 Comments
- 11/19/07: Primary Reviewer 2 Comments
- 11/19/07: Primary Reviewer 4 Comments
- 11/19/08: CIRB Approval with Query-Activation Amendment for Initial Review
- 09/17/08: CIRB Revision 3 Approval Letter (Protocol Version Date 08/26/08)
- 06/25/08: CIRB Approval Letter (Protocol Version Date 06/23/08)
- 06/25/08: CALGB Response to CIRB
- 03/27/08: CIRB Approval Pending Modification



- 02/26/08: CALGB Response to CIRB
- 01/09/08: CIRB Table of Initial Review
- 11/07/08: Minutes – Activation Amendment 1
- 03/17/08: Minutes - Group Response to Initial Review
- 12/07/07: Minutes - Initial Review

Pediatric CIRB Studies

COG-ACNS0333

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 02/21/08
- Protocol Version Date 02/21/08 - Highlighted Changes
- Protocol Version Date 11/15/07
- Protocol Version Date 11/15/07 - Highlighted Changes
- Protocol Version Date 09/12/06
- Protocol Version Date 09/12/06 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/21/08
- CIRB Application (Protocol Version Date 02/21/08)
- CIRB Application (Protocol Version Date 11/15/07)
- CIRB Application (Protocol Version Date 09/12/06)
- 12/13/07: Primary Reviewer 1 Comments
- 10/26/06: Primary Reviewer 1 Comments
- 10/26/06: Primary Reviewer 2 Comments
- 10/26/06: Primary Reviewer 3 Comments
- 03/17/08: CIRB Final Approval Letter (Protocol Version Date 02/21/08)
- 02/21/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/15/07)
- 01/15/08: CIRB Approval Pending Modification of the Group Response Letter (Protocol Version Date 11/15/07)
- 11/16/07: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/15/07)
- 11/29/06: CIRB Approval Pending Modification to Initial Review Letter (Protocol Version Date 09/12/06)
- 12/13/07: Minutes - Group Response to Initial Review
- 10/26/06: Minutes - Initial Review



Other Activity Posted:

ACOSOG-Z1041

Amendment Review (AR): Amendment #3 Protocol Version Date 09/18/08

Documents Posted:

- 12/10/08: Change Memo (Protocol Version Date 09/18/08)
- CIRB Application (Protocol Version Date 09/18/08)
- 12/03/08: ACOSOG Response to CIRB
- 11/26/08: CIRB Amendment 3 Approval with Query (Protocol Version Date 09/18/08)
- Protocol Version Date 09/18/08
- Informed Consent Document for Protocol Version Date 09/18/08 [Am3]
- 11/07/08: Primary Reviewer 1 Comments

CALGB-SWOG-C80405

Amendment Review (AR): [Nationwide Intravenous Leucovorin Shortage](#)

Documents Posted:

- 12/02/08: CIRB Acknowledgement-Leucovorin Shortage Memo
- 11/25/08: CALGB Nationwide Intravenous Leucovorin Shortage

CALGB-10201

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/02/07)
- 12/01/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/02/07)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 05/02/07
- June 2007 - Study Summary

CALGB-10501

Continuing Review (CR): Continuing Review December 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/05/08)
- 12/09/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/05/08)
- 10/01/08: Continuing Review Reminder Notice
- Protocol Version Date 02/05/08



- Informed Consent Document for Protocol Version Date 02/05/08 [Dec08 CR]
- 12/05/08: Pharmacist Comments
- 12/05/08: Pharmacist Comments (2)
- June 2008 - Study Summary

CALGB-10603

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

- CIRB Continuing Review Application (Protocol Version Date 02/05/08)
- 12/12/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/05/08)
- 10/01/08: Continuing Review Reminder Notice
- Protocol Version Date 02/05/08
- Informed Consent Document for Protocol Version Date 02/05/08 [Dec08 CR]
- June 2008 - Study Summary

CALGB-30610

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

- CIRB Continuing Review Application (Protocol Version Date 01/18/08)
- 12/12/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/18/08)
- 09/08/08: Continuing Review Reminder Notice
- Protocol Version Date 01/18/08
- Informed Consent Document for Protocol Version Date 01/18/08 [Dec08 CR]
- 12/05/08: Primary Reviewer 1 Comments
- June 2008 - Study Summary

CALGB-40601

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

- CIRB Continuing Review Application (Protocol Version Date 06/23/08)
- 09/11/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/23/08)
- 08/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/23/08



CALGB-80101

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/02/08: CIRB Acknowledgement of Protocol Notice - Leucovorin Shortage
- 11/25/08: CALGB Notice-Shortage of Leucovorin

COG-AALL0622

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/28/08)
- 11/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/08)
- 11/13/08: COG Response to Pediatric CIRB
- 11/06/08: CIRB Continuing Review Approval Pending Modification (Protocol Version Date 03/28/08)
- 09/08/08: CIRB Continuing Review Reminder Notice (Protocol Version Date 03/28/08)
- Protocol Version Date 03/28/08
- Informed Consent Document for Protocol Version Date 03/28/08 [Oct08 CR]

COG-AALL0631

****Temporarily Closed to Accrual by COG - Effective November 19, 2008****

Amendment Review (AR): Clarification of Definition of Lestaurtinib-Related DLTs on AALL0631

Documents Posted:

- 11/24/08: CIRB Acknowledgement of Clarification of the Definition of Lestaurtinib-Related Dose Limiting Toxicities
- 11/14/08: COG Clarification of definition of lestaurtinib-related DLTs

COG-AALL06N1

Amendment Review (AR): Amendment #1B - Study Reactivation Memo (Protocol Version Date 10/02/08)

Documents Posted:

- 07/29/08: COG Change Memo
- CIRB Application (Protocol Version Date 10/02/08)
- CIRB Application (Protocol Version Date 07/29/08)
- 11/25/08: CIRB Acknowledgement of COG AALL06N1 Reactivation



- 11/10/08: CIRB Amendment 1B Approval Letter (Protocol Version Date 10/02/08)
- 10/02/08: COG Response to CIRB
- 10/01/08: CIRB Amendment 1A Approval Pending Modification (Protocol Version 07/29/08)
- Protocol Version Date 10/02/08
- Protocol Version Date 10/02/08 Highlighted
- Protocol Version Date 07/29/08
- Protocol Version Date 07/29/08 Highlighted
- Informed Consent Document (1) for Protocol Version Date 10/02/08 [Am1B]
- Informed Consent Document (2) for Protocol Version Date 10/02/08 [Am1B]

COG-AAML0431

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/07/07)
- 12/11/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/07/07)
- 10/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/07/07
- Protocol Version Date 02/07/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/07/07
- 08/25/08: Study Progress Report
- 04/11/08: DSMC Report

COG-ACNS0333

Amendment Review (AR): Activation Amendment (Protocol Version Date 11/07/08)

Documents Posted:

- CIRB Application (Protocol Version Date 11/07/08)
- CIRB Application (Protocol Version Date 08/04/08)
- 12/08/08: Study Activation Notification Memo
- 11/25/08: CIRB Approval Activation Amendment Letter (Protocol Version Date 08/04/08)
- 11/07/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/04/08)
- 10/02/08: CIRB Approval Pending Modification Letter (Protocol Version Date 08/04/08)
- Protocol Version Date 11/07/08
- Protocol Version Date 11/07/08- Highlighted Changes
- Protocol Version Date 08/04/08
- Protocol Version Date 08/04/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 11/07/08



COG-ACNS0333

Continuing Review (CR): Continuing Review September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/12/06)
- 09/24/07: CIRB Continuing Review Approval Letter (Protocol Version Date 09/12/06)
- 08/14/07: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/12/06
- Protocol Version Date 09/12/06 - Highlighted Changes

COG-ACNS0333

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/21/08)
- 06/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/21/08)
- 05/09/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/21/08
- Protocol Version Date 02/21/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/21/08

COG-AEPI05N1

****Temporarily Closed to Accrual by COG - Effective December 11, 2008****

Amendment Review (AR): Temporary Closure to Accrual - Effective December 11, 2008

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Receipt Temporary Closure to Accrual Memo
- 12/12/08: COG Temporary Closure Memo

COG- AHOD0431

****Temporary Closure to Accrual Effective December 4, 2008****

Amendment Review (AR): Temporary Closure to Accrual Effective December 4, 2008

Documents Posted:

- 12/05/08: COG Notice-Temporarily Closed to New Patient Accrual
- 12/05/08: CIRB Acknowledgement-Temporary Closure to New Accrual



COG-ANBL0531

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/12/07).
- 11/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/12/07)
- 11/12/08: COG Response to Pediatric CIRB (Protocol Version Date 09/12/07)
- 11/07/08: CIRB Continuing Review Approval Pending Modification (Protocol Version Date 09/12/07)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/12/07
- Informed Consent Document (Group2) for Protocol Version Date 09/12/07
- Informed Consent Document (Group3) for Protocol Version Date 09/12/07
- Informed Consent Document (Group4) for Protocol Version Date 09/12/07
- Informed Consent Document (Residual or Recurrent) for Protocol Version Date 09/12/07
- 04/11/08: DSMC Letter
- Spring 2008 - Study Summary
- Fall 2008 - Study summary

COG-ANBL0532

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/29/07)
- 11/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/29/07)
- 11/12/08: COG Response to Pediatric CIRB (Protocol Version Date 05/29/07)
- 11/07/08: CIRB Continuing Review Approval Pending Modification (Protocol Version Date 05/29/07)
- 09/08/08: CIRB Continuing Review Reminder Notice (Protocol Version Date 05/29/07)
- Protocol Version Date 05/29/07
- Informed Consent Document (Part1) for Protocol Version Date 05/29/07 [Oct08 CR]
- Informed Consent Document (Part2) for Protocol Version Date 05/29/07 [Oct08 CR]
- 04/11/08: DSMC Letter
- Study Summary



COG-ASCT0431

Amendment Review (AR): Amendment #1B Clarification (Protocol Version Date 09/05/08)

Documents Posted:

- 11/26/08: CIRB Approval of ASCT0431 Amendment 1B - Clarification Memo
- 09/05/08: COG Change Memo (Protocol Version Date 09/05/08)
- Protocol Version Date 09/05/08 - Highlighted Changes: Clarification

ECOG-E5103

Continuing Review (CR): Continuing Review December 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/28/08)
- 12/12/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/28/08)
- 10/01/08: Continuing Review Reminder Notice
- Protocol Version Date 05/28/08
- Informed Consent Document for Protocol Version Date 05/28/08 [CR Dec08]
- 12/05/08: Primary Reviewer 1 Comments
- November 2008 - Study Summary
- 05/09/08: DMC Recommendations
- 12/27/07: New England Journal of Medicine Article

ECOG-E5202

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/01/08: CIRB Acknowledgement of Protocol Notice - Leucovorin Shortage
- 11/24/08: ECOG Notice-Shortage of Leucovorin

ECOG-E5202

Amendment Review (AR): Addendum 9 (Protocol Version Date 07/29/08)

Documents Posted:

- 07/29/08: ECOG Change Memo
- CIRB Application (Protocol Version Date 07/29/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/29/08)
- 12/03/08: CIRB Acknowledgement-Addendum 9 Posting
- 11/17/08: CIRB Addendum 9 Approval Letter (Protocol Version Date 07/29/08)
- 10/15/08: ECOG Response to CIRB



- 09/25/08: CIRB Approval Pending Modification (Protocol Version Date 07/29/08)
- Protocol Version Date 07/29/08
- Informed Consent Document for Protocol Version Date 07/29/08 [Add9]
- 09/05/08: Primary Reviewer 1 Comments
- 09/05/08: Minutes - Addendum 9 Review

ECOG-E5204

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/01/08: CIRB Acknowledgement of Protocol Notice - Leucovorin Shortage
- 11/24/08: ECOG Notice-Shortage of Leucovorin

NCCTG-N0147

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/01/08: CIRB Acknowledgement of Leucovorin Shortage "Dear Doctor" Letter
- 11/25/08: NCCTG Shortage of Leucovorin Physician Letter
- 11/24/08: ECOG Notice-Shortage of Leucovorin

NCCTG-N0147

Amendment Review (AR): **Principal Investigators Notice-Submission of Pathology Materials**

Documents Posted:

- 12/08/08: CIRB Acknowledgement-Pathology Submission Memo dated 11/26/08
- 11/26/08: NCCTG Principal Investigators Notice-Submission of Pathology Materials

NSABP-R-04

Amendment Review (AR): **Oxaliplatin Drug Supply Changes**

Documents Posted:

- 12/01/08: CIRB Acknowledgement of Receipt-Oxaliplatin Drug Supply Changes
- 11/14/08: NSABP Notice-Oxaliplatin Drug Supply Changes



Serious Adverse Events

Study: COG ADVL 0525
SAE Posted: IN200803001203 FU1, MX200805003208, MX200805003208 FU1, TW200804007295 FU1, PT200805001720 FU1, RU200512000467 FU1, CA200711000761 FU2, IT200805003183, KR200805003793, PT200805001720, DE200805006116, TW200804007295

Study: COG AEWS0521
SAE Posted: 1653936 FU2, 253621, 1653936 FU1, 257028 FU2

Study: ACOSOG Z1031
SAE Posted: 1351240 FU2

Study: CALGB 40502
SAE Posted: 14292320

Study: CALGB SWOG C80405
SAE Posted: 07-02-13577, 1285866

Study: ECOG E4599
SAE Posted: 265261, 265652

Study: ECOG E5103
SAE Posted: 265261, 265652

Study: ECOG E5202
AE Posted: 265261, 265652

Study: ECOG E5204
SAE Posted: 265261, 265652

Study: GOG 0213
SAE Posted: 265261, 265652

Study: GOG 0218
SAE Posted: 265261, 265652

Study: NCCTG N0723
SAE Posted: 265261, 265652

Study: NSABP B-34
SAE Posted: 200816114 SU 82 FU1, 200823590 SU96, 200824957 SU 98, 200829546 SU97, 200831463 SU 99

Study: NSABP B-38



SAE Posted: MX200808002967, SE200803005797, US200808001062

Study: NSABP B-40

SAE Posted: 1187600 FU1, 1466045, 249327, 253571 FU1, 265033, 265261, 265652, 265846, MX200808002967, SE200803005797, US200808001062

Study: NSABP C-08

SAE Posted: 1187600 FU1, 1466045, 249327, 263520, 263899, 263914, 265033, 265261, 265652, 265846

Study: RTOG 0320

SAE Posted: 2007SP018230 FU8, 2008SP000756 FU2

Study: RTOG 0436

SAE Posted: 07-02-12323, 07-02-12323 FU1, 08-02-14475, 08-02-14690, 08-02-14941, 08-02-14973, 08-02-15006

Study: RTOG 0522

SAE Posted: 07-02-12323, 07-02-12323 FU1, 08-02-14475, 08-02-14690, 08-02-14941, 08-02-14973, 08-02-15006

Study: RTOG 0525

SAE Posted: 2007SP018230 FU8, 2008SP000756 FU2

Study: SWOG S0777

SAE Posted: 1132738 FU1

Corrections to Previous Study Activity Updates

CALGB-SWOG-C80405

Amendment Review (AR) Update 5 Approval

Documents Posted:

12/09/08: CIRB Approval of Update 5 Correction letter 3

12/09/08: CIRB Correction to Outcome Letter Dated October 21, 2008

Correction:

The CALGB/SWOG amendment review approval letter dated October 21, 2008 contains an error. The original letter referred to the amendment as **Amendment #5** but the amendment name is **Update #5**.



SWOG-S0221

Amendment Review (AR) Recruitment Material
Documents Posted:

08/29/07: CIRB Approval of Recruitment Material

Participant Recruitment Information

Correction:

This Recruitment Material was inadvertently left off the NCI CIRB Web in 2007.

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.