



**NCI Central IRB Study Activity Update
February 15, 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

ECOG-E2905

Initial Review 2008 Approval

Documents Posted:

- Protocol Version Date 11/10/08
- Protocol Version Date 10/01/08
- Protocol Version Date 06/16/08
- Protocol Version Date 04/19/06
- Informed Consent Document for Protocol Version Date 11/10/08
- CIRB Application (Protocol Version Date 11/10/08)
- Summary of CIRB Application Revisions (Protocol Version Date 11/10/08)
- CIRB Application ((Protocol Version Date 06/16/08)
- 12/05/08: Primary Reviewer 1 Comments
- 07/21/08: Primary Reviewer 1 Comments
- 07/21/08: Primary Reviewer 3 Comments
- 07/21/08: Primary Reviewer 4 Comments
- 12/12/08: CIRB Activation Revision Approval Letter (Protocol Version Date 11/10/08)
- 10/08/08: CIRB initial Review Approval Letter (Protocol Version Date 10/01/08)
- 10/01/08: ECOG Response to CIRB
- 08/14/08: CIRB Approval Pending Modification (Protocol Version Date 06/16/08)
- 12/05/08: Minutes - Follow-up Revision Prior to Activation
- 07/21/08: Minutes - Initial Review



Other Activity Posted:

ACOSOG-Z1031

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

- CIRB Continuing Review Application (Protocol Version Date 05/07/08)
- 02/10/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/07/08)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 05/07/08
- Informed Consent Document for Protocol Version Date 05/07/08 [CR09]
- Informed Consent Document for Protocol Version Date 05/07/08: Genome Project [CR09]
- Informed Consent Document for Protocol Version Date 05/07/08: Tissue [CR09]
- 02/06/09: Primary Reviewer 1 Comments
- 01/08/09: DMC Minutes
- 06/18/08: DMC Minutes
- Study Summary

CALGB-100104

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

- CIRB Continuing Review Application (Protocol Version Date 04/04/08)
- 02/11/09: CIRB Continuing Review Approval Letter February 2009 (Protocol Version Date 04/04/08)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 04/04/08
- Informed Consent Document for Protocol Version Date 04/04/08 [Per CR 09]
- 02/06/09: Primary Reviewer 1 Comments
- 11/14/08: DSMB Report
- Study Summary Dated November 2008

CALGB-SWOG-C80405

Amendment Review (AR): Nationwide Intravenous Leucovorin Shortage
Documents Posted:

- 02/09/09: CIRB Revised Leucovorin Instructions dated 12/30/08 Approval Letter
- 12/30/08: CALGB Revised Leucovorin Instructions



COG-AALL0331

Amendment Review (AR): Amendment #2C - Study Reactivation (Protocol Version Date 09/04/08)

Documents Posted:

- 08/14/08: Primary Reviewer 1 Comments
- 08/14/08: 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-AALL0622

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-AALL06N1

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

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-AALL07P4

Amendment Review (AR): **Acknowledgement of COG AALL07P4 Updated Investigator's Brochure v3.0 for EZN-2285**

Documents Posted:

- 02/06/09: CIRB Acknowledgement of Updated Investigator's Brochure



COG-AAML05P1

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-AAML06P1

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-ACCL05C1

****Study Reactivation by COG - Effective February 2, 2009****

Amendment Review (AR): **CIRB Acknowledgement of COG ACCL05C1 Study Reactivation (Protocol Version Date 10/31/08)**

Documents Posted:

- 02/02/09: COG Reactivation Memo
- 01/30/09: CIRB Acknowledgement of COG ACCL05C1 Reactivation

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-ACNS0222

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-ACNS0332

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-ACNS0333

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

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-ACNS0423

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/12/07)
- 02/02/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/12/07
- Informed Consent Document for Protocol Version Date 02/12/07
- 10/07/08: DSMC Report



COG-ADVL0221

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-AEPI05N1

Continuing Review (CR): Continuing Review September 2008

Documents Posted:

- 10/27/08: Primary Reviewer 1 Comments
- 10/27/08: Minutes - Group Response to Tabled Continuing Review/Amendment Review
- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: Minutes - Continuing Review

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

Documents Posted:

- 10/27/08: Primary Reviewer 1 Comments
- 10/27/08: Minutes - Group Response to Tabled Continuing Review/Amendment Review

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

COG-AEWS0621

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/06/07)
- 02/02/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/06/07)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/06/07
- Informed Consent Document for Protocol Version Date 11/06/07
- 08/25/08: Study Progress Report



COG-ALTE05N1

Continuing Review (CR): Continuing Review September 2008

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-ANBL0531

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-ANBL0532

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-AOST0331

Amendment Review (AR): **CIRB Acknowledgement of COG AOST0331 Investigator's Brochure for PegIntron**

Documents Posted:

- 02/06/09: CIRB Acknowledgement of COG Investigator's Brochure

COG-AOST06P1

Amendment Review (AR): CIRB Acknowledgement of COG AOST06P1

Amendment #1

Documents Posted:

- CIRB Application (Protocol Version Date 01/20/09)
- 02/06/09: CIRB Acknowledgement of Amendment #1



- 02/03/09: CIRB Amendment #1 Approval Letter (Protocol Version Date 01/20/09)
- 01/20/09: COG Change Memo (Protocol Version Date 01/20/09)
- Protocol Version Date 01/20/09
- Protocol Version Date 01/20/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/20/09

COG-ARAR0332

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-AREN0532

Continuing Review (CR): Continuing Review September 2008

Documents Posted:

- 08/14/08: 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-AREN0533

Continuing Review (CR): Continuing Review September 2008

Documents Posted:

- 09/11/08: Primary Reviewer 1 Comments
- 09/11/08: 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-AREN03B2

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-ARET0231

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

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-ARET0321

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

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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

Amendment Review (AR): CIRB Acknowledgement of COG ARET0332
Amendment #2
Documents Posted:

- CIRB Application (Protocol Version Date 11/21/08)
- CIRB Application (Protocol Version Date 11/21/08) - Highlighted Changes
- 02/06/09: CIRB Acknowledgement of Amendment #2
- 02/02/09: CIRB Amendment #2 Approval Letter (Protocol Version Date 11/21/08)
- 01/23/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/21/08)
- 01/21/09: CIRB Approval Pending Modification Letter (Protocol Version Date 11/21/08)
- 11/21/08: COG Change Memo (Protocol Version Date 11/21/08)
- Protocol Version Date 11/21/08
- Protocol Version Date 11/21/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 11/21/08 - Observation Arm
- Informed Consent Document for Protocol Version Date 11/21/08 - Chemotherapy Arm
- 01/08/09: Primary Reviewer 1 Comments
- 01/08/09: Minutes - Amendment Review



COG-ASCT0431

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

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: 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-D9902

Amendment Review (AR): Amendment #10 (Protocol Version Date 07/24/08)
Documents Posted:

- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: Minutes - Amendment Review

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

ECOG-E1A05

Amendment Review (AR): Addendum #2 (Protocol Version Date 01/21/09)
Documents Posted:

- 01/29/09: 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)
- 02/03/09: CIRB Addendum 2 Approval Letter (Protocol Version Date 01/29/09)
- 09/29/08: OHRP - IRB Review of Protocol and Informed Consent Changes
- Protocol Version Date 01/29/09
- Informed Consent Document for Protocol Version Date 01/29/09 [Addendum 2]

ECOG-E1A06

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

- CIRB Continuing Review Application (Protocol Version Date 09/24/08)
- 02/05/09: CIRB Continuing Review Approval with query (Protocol Version 09/24/08)
- 11/07/08: Continuing Review Reminder Notice
- Protocol Version Date 09/24/08
- Informed Consent Document for Protocol Version Date 09/24/08 [Per CR09]



- 01/26/09: Primary Reviewer 1 Comments
- November 2008 - Study Summary
- 10/29/08 & 11/04/08 ECOG DMC Recommendations

ECOG-E5204

Amendment Review (AR): Update #4 (Protocol Version Date 01/21/09)
Documents Posted:

- 01/21/09: Change Memo (Protocol Version Date 01/21/09)
- CIRB Application (Protocol Version Date 01/21/09)
- Summary of CIRB Application Revisions (Protocol Version Date 01/21/09)
- 02/02/09: CIRB Update 4 Approval Letter (Protocol Version Date 01/21/09)
- Protocol Version Date 01/21/09 [Up4]
- Informed Consent Document for Protocol Version Date 01/21/09 [Up4]

GOG-0209

Amendment Review (AR): SHORTAGE OF CISPLATIN (UPDATE)
Documents Posted:

- 01/30/09: CIRB Approval of Cisplatin Shortage Memo Dated 01/09/09
- 01/09/09: GOG Shortage of Cisplatin Update

GOG-0219

Amendment Review (AR): SHORTAGE OF CISPLATIN (UPDATE)
Documents Posted:

- 01/30/09: CIRB Approval of Cisplatin Shortage Memo Dated 01/09/09
- 01/09/09: GOG Shortage of Cisplatin Update

RTOG-0522

Amendment Review (AR): Closure - Anticipated March 4, 2009
Documents Posted:

- 02/10/09: CIRB Acknowledgement of Pending Closure-Anticipated March 4, 2009
- 02/04/09: RTOG Notification of Pending Closure

RTOG-0617

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

- CIRB Continuing Review Application (Protocol Version Date 08/29/08)
- 02/06/09: CIRB Continuing Review Approval (Protocol Version 08/29/08)
- 01/06/09: CIRB Approval Pending Modifications (Protocol Version Date 08/29/08)
- 11/10/08: Continuing Review Reminder Notice



- Protocol Version Date 08/29/08
- Informed Consent Document for Protocol Version Date 08/29/08 [Per CR08]
- 12/05/08: Primary Reviewer 1 Comments
- 12/05/08: Minutes - Continuing Review
- 01/09/09: DMC Minutes

SWOG-S0337

Amendment Review (AR): Revision #1 (Protocol Version Date 12/30/08)

Documents Posted:

- CIRB Application (Protocol Version Date 12/30/08)
- Summary of CIRB Application Revisions (Protocol Version Date 12/30/08)
- 02/04/09: CIRB Acknowledgement of Revision 1 Posting
- 01/21/09: CIRB Revision 1 Approval Letter (Protocol Version Date 12/30/08)
- Protocol Version Date 12/30/08
- Informed Consent Document for Protocol Version Date 12/30/08 [Rev1]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 12/30/08
- 12/30/08: Change Memo (Protocol Version Date 12/30/08)

SWOG-S0600

Amendment Review (AR): Nationwide Shortage of Intravenous (IV) Leucovorin

Documents Posted:

- 02/06/09: CIRB Leucovorin Shortage Memo dated 1/1/09 Approval Letter
- 01/01/09: SWOG Nationwide Shortage of Intravenous (IV) Leucovorin memo

SWOG-S0600

Continuing Review (CR): Approval January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/29/08)
- 01/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 12/29/08)
- 12/03/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 04/10/08
- 01/26/09: Primary Reviewer 1 Comments
- 12/22/08: SAE Report
- October-November 2008 - Study Summary
- 10/31/08: Group DSMC Memo (Minutes)
- 06/06/08: Action Letter - CETUXIMAB



SWOG-S0777

Amendment Review (AR): Revision #2 (Protocol Version Date 01/26/09)
Documents Posted:

- 02/15/09: Change Memo (Protocol Version Date 01/26/09)
- CIRB Application (Protocol Version Date 01/26/09)
- Summary of CIRB Application Revisions (Protocol Version Date 01/26/09)
- 02/04/09: CIRB Revision 2 Approval Letter (Protocol Version Date 01/26/09)
- 09/29/08: OHRP-IRB Review of Protocol and Informed Consent Changes
Protocol Version Date 01/26/09
- Informed Consent Document for Protocol Version Date 01/26/09 [Per Rev2]
- Informed Consent Document (Notes for Local Institution) for Protocol
Version Date 01/26/09

Serious Adverse Events

Study: CALGB 30607
SAE Posted: 2008055824 FU2

Study: CALGB 40302
SAE Posted: 100184, 15303

Study: CALGB 40502
SAE Posted: 1940244

Study: CALGB 40503
SAE Posted: 1820686 FU1, 260365 FU1

Study: CALGB 80203
SAE Posted: 08-02-14973

Study: CALGB 80303
SAE Posted: 1820686 FU1, 260365 FU1

Study: CALGB 90206
SAE Posted: 1820686 FU1, 260365 FU1

Study: CALGB 90401
SAE Posted: 1820686 FU1, 260365 FU1

Study: CALGB ECOG 100104
SAE Posted: 1779801 FU1

Study: CALGB SWOG C80405
SAE Posted: 1820686 FU1



Study: NCIC CTG MA27
SAE Posted: MA27-25, MA27-26, MA27-27

Study: NCCTG N0147
SAE Posted: 08-02-15301 FU1

Study: NSABP B-34
SAE Posted: 200824407 SU93 FU2, 200828012 SU105 FU2, 200828565 SU107, 200829635 SU110, 200835467 SU106, 200835467 SU106 FU1, 200836245 SU108, 200836438 SU109, TR-2007-006800 SU44 FU1, 200823590 SU96 FU1, 200829635 SU110 FU1, 200837950 SU111, 200838304 SU112

Study: NSABP B-40
SAE Posted: 263914 FU5, 2699963 FU2, 270229, 252250, 270965, 271156, 252250 FU1, 265652 FU3, 270965 FU2, 272175

Study: NSABP C-08
SAE Posted: 1354425 FU1, 1477246, 1809808, 258964 FU1, 267119 FU2, 1118620, 1205368, 1475911, 1729567, 1803957, 1859262 FU1, 265652 FU3, 270229

Study: RTOG 0436
SAE Posted: 08-02-14462, 08-02-14619 FU1, 08-02-15188 FU1, 08-02-15290 FU1, 08-02-15292, 08-02-15301 FU1, 08-02-15483, 08-02-15528 FU1, 08-02-15541, 08-02-15603, 08-02-15603 FU1, 08-02-15660

Study: RTOG 0522
SAE Posted: 08-02-14462, 08-02-14619 FU1, 08-02-15188 FU1, 08-02-15290 FU1, 08-02-15292, 08-02-15301 FU1, 08-02-15483, 08-02-15528 FU1, 08-02-15541, 08-02-15603, 08-02-15603 FU1, 08-02-15660

Study: SWOG S0518
SAE Posted: 1187600 FU1, 1199283 FU1, 1226348 FU1, 1466045, 1466045 FU1, 1636469, 1653936 FU1, 1653936 FU2, 1820686 Fu1, 1843518, 257028 Fu2, 260365 FU1, 263899 FU1

Study: SWOG S0600
SAE Posted: 1187600 FU1, 1226348 FU1, 1466045, 1466045 FU1, 1477246, 1506455, 1506455 FU1, 1653936 FU2, 1820686 FU1, 1859262, 253621, 257028 FU2, 260365 FU1, 263899 FU1, 267119 FU2, 556768 FU1, 1636469, 1843518

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.