



NCI Central IRB Study Activity Update

March 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.

Pediatric CIRB Studies

COG-AAML0631

Initial Review 2009 Approval
Documents Posted:

- Protocol Version Date 01/14/09
- Protocol Version Date 01/14/09 - Highlighted Changes
- Protocol Version Date 10/01/08
- Protocol Version Date 10/01/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/14/09 - PARENTAL PERMISSION
- Informed Consent Document for Protocol Version Date 01/14/09 - BONE MARROW
- CIRB Application (Protocol Version Date 01/14/09)
- CIRB Application (Protocol Version Date 10/02/08)
- 11/13/08: Primary Reviewer 1 Comments
- 11/13/08: Primary Reviewer 2 Comments
- 03/06/09: CIRB Acknowledgement of COG AAML0631 Activation Memo
- 02/05/09: CIRB Final Approval Letter (Protocol Version Date 01/14/09)
- 01/14/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 01/14/09)
- 12/12/08: CIRB Approval Pending Modification of Initial Review Letter (Protocol Version Date 10/01/08)
- 10/01/08: COG Response Letter (Protocol Version Date 10/01/08)
- 11/13/08: Minutes - Initial Review

Other Activity Posted:

ACOSOG-Z1031

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

- 02/06/09: Minutes – Continuing Review

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



ACOSOG-Z6051

Amendment Review (AR): Amendment 1 (Protocol Version Date 01/26/09)
Documents Posted:

- 01/26/09: ACOSOG Change Memo (Protocol Version Date 01/26/09)
- CIRB Application (Protocol Version Date 01/26/09)
- 02/26/09: CIRB Amendment 1 Approval Letter (Protocol Version Date 01/26/09)
- ACOSOG Surgeon Skill Verification Checklist
- Protocol Version Date 01/26/09
- Protocol Version Date 01/26/09 – Highlighted
- Informed Consent Document for Protocol Version Date 01/26/09 [Am1]
- 02/23/09: Primary Reviewer 1 Comments

ACOSOG-Z6051

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

- 01/09/09: Minutes - Recruitment Material

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

ACOSOG-Z6051

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

- 02/06/09: Minutes – Continuing Review

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

CALGB-30607

Amendment Review (AR): Update 1 (Protocol Version Date 02/10/09)
Documents Posted:

- 02/23/09: CALGB Change Memo
- CIRB Application (Protocol Version Date 02/10/09)
- 02/24/09: CIRB Update 1 Approval Letter (Protocol Version Date 02/10/09)
- 02/24/09: Sunitinib Action Letter Notice
- Protocol Version Date 02/10/09
- Informed Consent Document for Protocol Version Date 02/10/09 [Up1]
- OHRP: IRB Review of Protocol and Informed Consent Changes

CALGB-80203



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

- CIRB Continuing Review Application (Protocol Version Date 02/09/07)
- 03/04/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/09/07)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 02/09/07
- Informed Consent Document for Protocol Version Date 02/09/07
- Final Report - Author A. Venook et. al
- DSMB Report 10/15/05
- Study Summary Dated June 2005

CALGB-SWOG-C80405

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

- 01/26/09: Minutes - Drug Shortage Revised Letter

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

CALGB-100104

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

- 02/06/09: 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-AALL03B1

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

- 02/12/09: Primary Reviewer 1 Comments

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: Primary Reviewer 1 Comments



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: Primary Reviewer 1 Comments

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

COG-ACNS0621

Amendment Review (AR): Amendment #1 (Protocol Version Date 02/27/09)
Documents Posted:

- 03/02/09: COG Change Memo (Protocol Version Date 02/27/09)
- CIRB Application (Protocol Version Date 02/27/09)
- 03/10/09: CIRB Acknowledgement of Cilengitide Action Letter
- 03/09/09: COG Action Letter Notice
- 03/05/09: CIRB Amendment 1 Approval Letter (Protocol Version Date 02/27/09)
- OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol Version Date 02/27/09
- Protocol Version Date 02/27/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/27/09 [Am1]

COG-AEWS07B1

Amendment Review (AR): Amendment #1 (Protocol Version Date 02/10/09)
Documents Posted:

- CIRB Application (Protocol Version Date 02/10/09)
- CIRB Application (Protocol Version Date 01/13/09)
- 03/02/09: COG AEWS07B1 Amendment #1 Activation Memo
- 02/18/09: CIRB Approval of COG AEWS07B1 Amendment #1 (Protocol Version Date 02/19/09)
- 02/10/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/10/09)
- 02/02/09: CIRB Approval Pending Modification Letter (Protocol Version Date 01/13/09)
- 01/13/09: COG Change Memo (Protocol Version Date 01/13/09)
- Protocol Version Date 02/10/09
- Protocol Version Date 02/10/09 - Highlighted Changes
- Protocol Version Date 01/13/09



- Protocol Version Date 01/13/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/10/09: At Initial Diagnosis
- Informed Consent Document for Protocol Version Date 02/10/09: Recurrence

COG-AEPI05N1

Amendment Review (AR): Amendment #3 (Protocol Version Date 01/22/09)
Documents Posted:

- CIRB Application (Protocol Version Date 01/22/09)
- 03/02/09: COG AEPI05N1 Amendment #3 Activation Memo
- 02/24/09: CIRB Approval of COG AEPI05N1 Amendment #3 (Protocol Version Date 01/22/09)
- 01/22/09: COG Change Memo (Protocol Version Date 01/22/09)
- Protocol Version Date 01/22/09
- Protocol Version Date 01/22/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/22/09 - Case Subjects
- Informed Consent Document for Protocol Version Date 01/22/09 - Control Subjects

COG-ANBL0532

Amendment Review (AR): Activation Amendment #1B (Protocol Version Date 01/28/09)
Documents Posted:

- CIRB Application (Protocol Version Date 01/28/09)
- CIRB Application (Protocol Version Date 12/12/08)
- 03/02/09: COG ANBL0532 Amendment #1 Activation Memo
- 02/03/09: CIRB Approval of COG ANBL0532 Amendment #1B (Protocol Version Date 01/28/09)
- 01/28/09: COG Change Memo-Updated (Protocol Version Date 01/28/09)
- 01/28/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 12/12/08)
- 01/21/09: CIRB Approval Pending Modification Letter (Protocol Version Date 12/12/08)
- 12/12/08: COG Change Memo (Protocol Version Date 12/12/08)
- Protocol Version Date 01/28/09
- Protocol Version Date 01/28/09 - Highlighted Changes
- Protocol Version Date 12/12/08
- Protocol Version Date 12/12/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/28/09 - Induction Therapy



- Informed Consent Document for Protocol Version Date 01/28/09 - Randomized to Consolidation Therapy
- Informed Consent Document for Protocol Version Date 01/28/09 - Non-Randomly Consolidation Therapy
- 01/08/09: Primary Reviewer 1 Comments
- 01/08/09: Minutes - Amendment Review

Amendment Review (AR): **CIRB Acknowledgement of COG ANBL0532 Clarification of Amendment CIRB Numbering**

Documents Posted:

- 03/06/09: Acknowledgement of Clarification of Amendment Numbering
- 03/06/09: COG Notification of Clarification of Amendment Numbering

COG-ASCT0631

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- 02/12/09: Primary Reviewer 1 Comments

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: Primary Reviewer 1 Comments

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

ECOG-E1A05

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- 01/09/09: 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-E1A06

Continuing Review (CR): Continuing Review January 2009

Documents Posted:



- 01/26/09: 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-E1305

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/19/08)
- 03/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/19/08)
- 01/02/09: Continuing Review Reminder Notice
- Protocol Version Date 11/19/08
- Informed Consent Document for Protocol Version Date 11/19/08 [CR09]
- November 2008 Study Summary
- 03/06/09: Primary Reviewer 1 Comments

ECOG-E1505

Amendment Review (AR): Addendum #6 (Protocol Version Date 01/07/09)

Documents Posted:

- 01/07/09: ECOG Change Memo-Group Response to CIRB (Protocol Version Date 01/07/09)
- CIRB Amendment Review Application (Protocol Version Date 01/07/09)
- Summary of CIRB Application Revisions (Protocol Version Date 01/07/09)
- 03/10/09: Acknowledgement of Activation Effective April 1, 2009
- 01/22/09: CIRB Approval Addendum 6 (Protocol Version Date 01/07/09)
- 01/06/09: CIRB Approval Pending Modification
- Protocol Version Date 01/07/09
- Informed Consent Document for Protocol Version Date 01/07/09 [Add6]
- 12/05/08: Primary Reviewer 1 Comments
- 12/05/08: Minutes - Addendum #6 Review

ECOG-E2603

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- 01/26/09: 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-E5204

Continuing Review (CR): Continuing Review January 2009



Documents Posted:

- 01/09/09: 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-PACCT-1

Amendment Review (AR): Addendum #4 (Protocol Version Date 12/24/08)

Documents Posted:

- 01/26/09: Minutes – Addendum 4

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

GOG-0209

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

Documents Posted:

- 01/26/09: Minutes – Drug Shortage Notice

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

GOG-0219

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

Documents Posted:

- 01/26/09: Minutes – Drug Shortage Notice

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

NCCTG-N0723

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/28/08)
- 03/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/28/08)
- 02/05/09: Continuing Review Reminder Notice
- Protocol Version Date 10/28/08
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 10/28/08



- Informed Consent Document for Protocol Version Date 10/28/08 [CR09]
- 03/06/09: Primary Reviewer 1 Comments

NCIC CTG-MA.27

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

- 01/09/09: Minutes – Continuing Review

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

NSABP-B-38

Amendment Review (AR): Acknowledgement of IB Update dated 09/26/08
Documents Posted:

- 02/27/09: CIRB Acknowledgement of Gemcitabine IB Update

NSABP-B-40

Amendment Review (AR): Acknowledgement of IB Update dated 09/26/08
Documents Posted:

- 02/27/09: CIRB Acknowledgement of Gemcitabine IB Update

NSABP-B-43

Amendment Review (AR): CIRB Acknowledgement of Updated Trastuzumab Investigator Brochure
Documents Posted:

- 02/27/09: CIRB Acknowledgement of Trastuzumab IB update

RTOG-0522

****Closed to Accrual – Effective March 3, 2009****

Documents Posted:

- 03/05/09: CIRB Acknowledgement of Receipt - Closure to Accrual 03/03/09
- 03/03/09: RTOG Closure to Accrual Notice
- 02/10/09: CIRB Acknowledgement of Pending Closure-Anticipated March 4, 2009
- 02/04/09: RTOG Notification of Pending Closure

RTOG-0617

Amendment Review (AR): Recruitment Material
Documents Posted:



- 02/26/09: CIRB Recruitment Material Approval Letter
- January 2009 - Participant Recruitment Brochure
- 02/23/09: Primary Reviewer 1 Comments

SWOG-9007

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

- CIRB Continuing Review Application (Protocol Version Date 06/23/08)
- 03/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/23/08)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 06/23/08
- Informed Consent Document for Protocol Version Date 06/23/08 [CR09]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 06/23/08
- 03/06/09: Primary Reviewer 1 Comments
- 01/14/09: Blood Journal Abstract
- October-November 2008 Study Summary

SWOG-S0106

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

- CIRB Continuing Review Application (Protocol Version Date 03/28/08)
- 03/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/08)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 03/28/08
- Informed Consent Document for Protocol Version Date 03/28/08 [Per March 09 CR]
- 01/14/09: SAE Listing
- 10/31/08: DSMC Minutes
- October 2008: Study Summary
- 03/06/09: Primary Reviewer 1 Comments

SWOG-S0307

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

- 01/26/09: Minutes – Continuing Review

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



SWOG-S0309

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

- CIRB Application (Protocol Version Date 02/12/07)
- 03/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 02/12/07
- October 2007 - Study Summary
- 03/06/09: Primary Reviewer 1 Comments

SWOG-S0337

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

- CIRB Continuing Review Application (Protocol Version Date 12/30/08)
- 03/10/09: CIRB Continuing Review Approval with Query Letter (Protocol Version Date 12/30/08)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 12/30/08
- Informed Consent Document for Protocol Version Date 12/30/08 [CR09]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 12/30/08
- 03/06/09: Primary Reviewer 1 Comments
- 10/31/08: DSMC Minutes
- October-November 2008 - Study Summary

SWOG-S0600

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

- 01/26/09: Minutes – Drug Shortage Notice

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

SWOG-S0600

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

- 01/26/09: Minutes – Continuing Review

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



SWOG-S9910

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/29/07)
- 03/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/29/07)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 11/29/07
- 03/06/09: Primary Reviewer 1 Comments
- October 2008: Report of Study

SWOG-S9925

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/06/09)
- 03/12/09: CIRB Continuing Review Approval Letter Continuing Review (Protocol Version Date 01/06/09)
- 01/05/09: Continuing Review Reminder Notice
- Protocol Version Date 01/06/09
- 03/06/09: Primary Reviewer 1 Comments

Serious Adverse Events

Study: ECOG E1A05

SAE Posted: 1203812, 1358268, 1567424, 1779801 FU1, 1898864, 1898864 FU1

Study: ECOG E1A06

SAE Posted: 1358268, 1779801 FU1, 1898864, 1898864 FU1

Study: ECOG E1305

SAE Posted: 1729567, 1809808

Study: ECOG E4A03

SAE Posted: 1358268, 1779801 FU1, 1898864, 1898864 FU1

Study: NSABP B-34

SAE Posted: 200839971 SU115

Study: NSABP B-38

SAE Posted: FR200806005794, FR200811005873, SE200803005797 FU1

Study: NSABP B-40



SAE Posted: 272175 FU1, 272529, FR200806005794, FR200811005873, SE200803005797 FU1

Study: SWOG S0518

SAE Posted: 1118620, 1205368, 1205368 FU1, 1324148, 1433885, 1475911, 1580693, 1729567, 1803957, 1803957 FU1, 1809808, 1809808 FU1, 1881593, 270229

Study: SWOG S0777

SAE Posted: 056C50137110778 FU2, 1203812 FU1, 1358268, 1567424, 1779801, 1779801 FU1, 1898864, 1898864 FU1, 1966235 FU1

Study: COG AALL0631

SAE Posted: US022349 FU1, US023376, US024469 FU1

Study: COG AAML06P1

SAE Posted: US022349 FU1, US023376, US024469 FU1

Study: COG AAML07P1

SAE Posted: 1203812

Study: COG ADVL0221

SAE Posted: DE-JNJFOC-20080904677, FR-JNJFOC-20080505419 FU2, GB-JNJFOC-20080901441 FU1, GB-JNJFOC-20080901441 FU2, GB-JNJFOC-2008091441, US-JNJFOC-20080400179 FU6, US-JNJFOC-20080705088, US-JNJFOC-2008075088 FU3, US-JNJFOC-20080901828, US-JNJFOC-20080902386, US-JNJFOC-20080902386 FU1

Study: COG ADVL0525

SAE Posted: BE200808003736 FU2, BR200809004647 FU1, BR200809004674, DE200802002043 FU4, DE200808002649 FU1, DE200808003152 FU1, DE200809001485, DE200809001485 FU1, ES200709003440 FU1, HU200710007592 FU2, IN200809001078, IN200809001078 FU1, KR200804005778 FU1, KR200809001401, KR200809005737 FU1, KR200810003143, US200808003920 FU1, US200808003920 FU2

Study: COG AEWS0521

SAE Posted: 1226348 FU1, 1285866, 1466045 FU1, 1506455, 1820686 FU1

Study: COG AHOD0521

SAE Posted: 1358268

If you have any questions about the CIRB Initiative, please contact the CIRB at ncicirbcontact@emmes.com.