



NCI Central IRB Study Activity Update September 30, 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 – AAML07P1

Initial Review 2007 Approval

Documents Posted:

- 01/28/08: COG Response to CIRB Approval Pending Modification to Initial Review

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

COG – ALTE07C1

Initial Review 2008 Approval

Documents Posted:

- Protocol Version Date 07/28/08
- Protocol Version Date 07/28/08 - Highlighted Changes
- Protocol Version Date 03/26/08
- Protocol Version Date 03/26/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 07/28/08
- CIRB Application (Protocol Version Date 07/28/08)
- CIRB Application (Protocol Version Date 03/26/08)
- 05/08/08: Primary Reviewer 1 Comments
- 05/08/08: Primary Reviewer 2 Comments
- 05/08/08: Primary Reviewer 3 Comments
- 08/27/08: CIRB Approval Letter (Protocol Version Date 07/28/08)
- 07/28/08: Change Letter (Protocol Version Date 07/28/08)
- 05/28/08: CIRB Tabled Letter (Protocol Version Date 03/26/08)
- 03/26/08: COG Cover Letter (Protocol Version Date 03/26/08)
- 05/08/08: Minutes - Initial Review

Other Activity Posted:

ACOSOG-Z1041

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/17/08)
- 09/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/17/08)
- 07/11/08: Continuing Review Reminder Notice
- Protocol Version Date 03/17/08
- Informed Consent Document (Step 1) for Protocol Version Date 03/17/08
- Informed Consent Document (Step 2) for Protocol Version Date 03/17/08
- 09/15/08: Primary Reviewer 1 Comments
- 06/18/08: DSMB Report
- Report of Studies
- SAE Report

CALGB-90203

Amendment Review (AR): Update #3 (Protocol Version Date 07/17/08)

Documents Posted:

- 09/15/08: Change Memo (Protocol Version Date 07/17/08)
- CIRB Application (Protocol Version Date 07/17/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/17/08)
- 08/20/08: CIRB Update 3 Approval Letter (Protocol Version Date 07/17/08)
- 07/18/08: CALGB Cover Letter
- Protocol Version Date 07/17/08 [Per Up3]
- Informed Consent Document for Protocol Version Date 07/17/08 [Per Up3]
- 08/18/08: Minutes - Update 3

CALGB-140503

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/15/08)
- 09/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/15/08)
- 08/07/08: Continuing Review Reminder Notice (Protocol Version Date 02/15/08)
- Protocol Version Date 02/15/08
- Informed Consent Document for Protocol Version 02/15/08 [Per Sep 08 CR]
- 09/15/08: Primary Reviewer 1 Comments
- 06/27/08: DSMB Report
- December 2007 – Study Summary

CALGB-SWOG-C80405

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/27/08)
- 09/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/27/08)
- 08/07/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/27/08
- Informed Consent Document for Protocol Version Date 08/27/08 [Per Sep 08 CR]
- 09/15/08: Primary Reviewer 1 Comments
- 06/06/08: Physician Letter
- 06/06/08: Research Participant Letter
- 01/15/08: DSMB Report
- November 2007 - Study Summary

CALGB-SWOG-C80405

Amendment Review (AR): Update #5 (Protocol Version Date 08/27/08)

Documents Posted:

- 09/15/08: Change Memo (Protocol Version Date 08/27/08)
- CIRB Application (Protocol Version Date 08/27/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/27/08)
- 09/19/08: CIRB Update 5 Approval Correction Letter (Protocol Version Date 08/27/08)
- 09/05/08: CIRB Update 5 Approval Letter (Protocol Version Date 08/27/08)
- Protocol Version Date 08/27/08
- Informed Consent Document for Protocol Version Date 08/27/08 [Per Up5]

Notice of Continued Suspension To Accrual

Documents Posted:

- 09/24/08: CIRB Acknowledgement of Receipt of Accrual Suspension Update
- 09/09/08: CALGB Memo Regarding Suspension of Accrual

COG – AAML0523

Continuing Review (CR): Continuing Review August 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 95/05/08)
- 08/27/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/06/08)

- 07/11/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/06/08
- Informed Consent Document for Protocol Version Date 05/06/08
- 04/16/08: DSMC Report
- 02/04/08: Study Progress Report

COG – ACCL0431

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

- CIRB Continuing Review Application (Protocol Version Date 01/24/08)
- 08/29/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/24/08)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/24/08
- Informed Consent Document for Protocol Version Date 01/24/08

COG – ACCRN07

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

- Information Sheet for ACCRN07 (Protocol Version Date 08/06/08)
- Reminder Memoranda/Permission Forms for ACCRN07 (Protocol Version Date 08/06/08)

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

COG – AEWS0521

Amendment Review (AR): CIRB Acknowledgement of Temporary Closure to Accrual
Documents Posted:

- 09/17/08: CIRB Acknowledgement of Temporary Closure to Accrual
- 09/05/08: Temporary Suspension of Accrual of Study AEWS0521

****Temporarily Closed to Accrual by COG - Effective September 2, 2008****

COG – AREN0533

Amendment Review (AR): Amendment #1 (Protocol Version Date 06/17/08)
Documents Posted:

- CIRB Application (Protocol Version Date 06/17/08)
- CIRB Application (Protocol Version Date 09/28/07)
- 09/08/08: COG Change Memo (Protocol Version Date 06/17/08)

- 08/27/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 06/17/08)
- 06/20/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/17/08)
- 01/15/08: CIRB Approval Pending Modification Letter (Protocol Version Date 09/28/07)
- 10/11/07: COG Change Letter (Protocol Version Date 09/28/07)
- Protocol Version Date 06/17/08
- Protocol Version Date 06/17/08 - Highlighted Changes
- Protocol Version Date 09/28/07
- Protocol Version Date 09/28/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 06/17/08
- 12/13/07: Primary Reviewer 1 – Comments
- 12/13/07: Minutes - Amendment Review

ECOG-E2902

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/08/07)
- 09/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/08/07)
- 08/07/08: Continuing Review Reminder Notice
- Protocol Version Date 11/08/07
- Informed Consent Document for Protocol Version Date 11/08/07 [Per Sep 08 CR]
- 09/15/08: Primary Reviewer 1 Comments
- June 2008 - Study Summary
- 05/09/08: DSMB Report

ECOG-E4402

Amendment Review (AR): Addendum #5 (Protocol Version Date 04/17/08)

Documents Posted:

- 04/17/08: Change Memo (Protocol Version Date 04/17/08)
- CIRB Application (Protocol Version Date 04/17/08)
- Summary of CIRB Application Revisions (Protocol Version Date 04/17/08)
- 06/05/08: CIRB Addendum 5 Approval Letter (Protocol Version Date 04/17/08)
- Protocol Version Date 04/17/08 [Per Add5]
- 05/19/08: Minutes Addendum 5 Review

GOG-0209

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/12/08)
- 09/25/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/12/08)
- 07/14/08: Continuing Review Reminder Notice (Protocol Version Date 05/12/08)
- Protocol Version Date 05/12/08 [Per Sep08 CR]
- Informed Consent Document for Protocol Version Date 05/12/08 [Per Sep08 CR]
- 09/05/08: Primary Reviewer 1 Comments
- July 2008 - Study Summary
- 01/26/08: DSMB Report

NCCTG-N0147

Amendment Review (AR): Addendum #9 (Protocol Version Date 07/21/08)
Documents Posted:

- 09/24/08: CIRB Acknowledgement of Receipt-Addendum 9 Protocol Date Discrepancy
- 09/11/08: NCCTG Memo Clarifying Protocol Version Dates

Notice of Editorial Correction to Addendum 9
Documents Posted:

- 09/09/08: CIRB Acknowledgement of Receipt-Addendum 9 Correction Memo
- 08/27/08: NCCTG Editorial Correction Memo-Addendum 9

NCCTG-N0147

Amendment Review (AR): Update #3 (Protocol Version Date 08/12/08)
Documents Posted:

- 08/18/08: Change Memo (Protocol Version Date 08/12/08)
- CIRB Application (Protocol Version Date 08/12/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/12/08)
- 09/11/08: CIRB Update 3 Approval Letter (Protocol Version Date 08/12/08)
- Protocol Version Date 08/12/08
- Informed Consent Document for Protocol Version Date 08/12/08 [Per Up3]

NCIC CTG-PR.11

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

- CIRB Continuing Review Application (Protocol Version Date 04/07/08)

- 09/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/07/08)
- 08/07/08: Continuing Review Reminder Notice
- Protocol Version Date 04/07/08
- Informed Consent Document for Protocol Version Date 04/07/08 [Per Sep 08 CR]
- 09/15/08: Primary Reviewer 1 Comments
- 05/02/08: DSMB Report

NSABP-B42

Closure of Optional Registration Program

Documents Posted:

- 09/11/08: CIRB Acknowledgement of Receipt – Closure of Optional Registration Program
- 09/05/08: NSABP Optional Registration Closure Notice

RTOG-0232

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/11/08)
- 09/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/11/08)
- 08/07/08: Continuing Review Reminder Notice
- Protocol Version Date 01/11/08
- Informed Consent Document for Protocol Version Date 01/11/08 [Per Sep 08 CR]
- 09/15/08: Primary Reviewer 1 Comments
- June 2008 - Study Summary
- 01/11/08: DSMB Report

RTOG-0436

Continuing Review (CR): Approval September 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/28/08)
- 09/18/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/08)
- 07/14/08: 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 [Per Sep 08 CR]
- 09/15/08: Primary Reviewer 1 Comments

- June 2008 - Study Summary

SWOG-S0106

Correction Memo: Error in Arm 1 Study Calendar Documents Posted:

- 09/24/08: CIRB Acknowledgement of Receipt of Correction Memo
- 09/15/08: SWOG Correction Letter

SWOG-S0226

Amendment Review (AR): Revision #3 Approval -8/29/08 (Protocol Version Date 08/11/08)

Documents Posted:

- 08/11/08: Change Memo (Protocol Version Date 08/11/08)
- CIRB Application (Protocol Version Date 08/11/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/11/08)
- 08/29/08: CIRB Revision 3 Approval Letter (Protocol Version Date 08/11/08)
- Protocol Version Date 08/11/08 [Per Rev3]
- Informed Consent Document for Protocol Version Date 08/11/08 [Per Rev3]

SWOG-S0307

Amendment Review (AR): Revision #4 Approval -8/22/08 (Protocol Version Date 07/25/08)

Documents Posted:

- 07/25/08: Change Memo (Protocol Version Date 07/25/08)
- CIRB Application (Protocol Version Date 07/25/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/25/08)
- 08/25/08: CIRB Revision 4 Approval Letter (Protocol Version Date 07/25/08)
- Protocol Version Date 07/25/08
- Informed Consent Document for Protocol Version Date 07/25/08 [Per Rev4]

Serious Adverse Events

Study: ACOSOG Z1031

SAE Posted: 1752507, 1213376, 1613765, 1997021 FU2

Study: CALGB 80203

SAE Posted: 08-02-14322, 08-02-13981

Study: CALGB 80303
SAE Posted: 254163 FU2

Study: CALGB 90206
SAE Posted: 254163 FU2

Study: CALGB 90401
SAE Posted: 254163 FU2

Study: CALGB ECOG 100104
SAE Posted: 056-C5013-07110778 FU2

Study: CALGB-SWOG C80405
SAE Posted: 08-02-14322, 08-02-14660 FU1

Study: ECOG E1A05
SAE Posted: 1132738 FU1, 056-C5013-07110778 FU2

Study: ECOG E1A06
SAE Posted: 1132738 FU1, 056-C5013-07110778 FU2

Study: ECOG E4A03
SAE Posted: 1132738 FU1, 056-C5013-07110778 FU2

Study: ECOG E1105
SAE Posted: 254163 FU2

Study: ECOG E2603
SAE Posted: 1633079 FU1, 1838547 FU1

Study: ECOG E1305
SAE Posted: 254163 FU2

Study: ECOG E1505
SAE Posted: 254163 FU2

Study: ECOG E2100
SAE Posted: 254163 FU2

Study: ECOG E2805
SAE Posted: 1771160 FU1, 1838547 FU1

Study: ECOG E2905
SAE Posted: 056-C5013-07110778 FU2

Study: ECOG E4599

SAE Posted: 254163 FU2

**Study: ECOG E5103
SAE Posted: 254163 FU2**

**Study: ECOG E5202
SAE Posted: 254163 FU2**

**Study: ECOG E5204
SAE Posted: 254163 FU2**

**Study: GOG 0213
SAE Posted: 1653936 FU1**

**Study: GOG 0218
SAE Posted: 1653936 FU1**

**Study: NCCTG N0147
SAE Posted: 08-02-14322, 08-02-14426 FU1, 08-02-14619, 08-02-13884 FU1,
08-02-14660 FU1**

**Study: NSABP B-34
SAE Posted: 200821861 SU86, 200821886 SU87, 200822387 SU88,
200818891 Safety Update 89**

**Study: NSABP B-38
SAE Posted: AR200805002972, FR200806004114, US200803001632 FU1**

**Study: NSABP B-40
SAE Posted: 253621, 257028 FU2, 263520, 263914, FR200806004114,
US200803001632, 231325 FU5, 260365 FU1, 260365 FU2, 262431 FU1,
263520 FU1, 263899 FU1, 263914 FU1, 264926, 263899**

**Study: NSABP C-08
SAE Posted: 253621, 257028 FU2, 260365 FU1, 260365 FU2, 262431 FU1,
263520 FU1, 263899 FU1, 263914 FU1, 264926**

**Study: RTOG 0320
SAE Posted: 2008SP009832, 2008SP010385, 2007SP007552 FU9,
2007SP018230 FU7, 2008SP003086 FU1, 2008SP009306 FU1**

**Study: RTOG 0436
SAE Posted: 08-02-14322, 08-02-14660 FU2, 08-02-14677 FU1, 08-02-14713,
08-02-13884 FU1, 08-02-14426 FU1, 08-02-14660, 08-02-14660 FU1**

Study: RTOG 0522

SAE Posted: 08-02-14322, 08-02-14481, 08-02-14660 FU2, 08-02-14677 FU1, 08-02-14713, 08-02-13884, 08-02-13884 FU1, 08-02-14337, 07-02-13583 FU1, 05-02-05850 FU3

Study: RTOG 0525
SAE Posted: 2008SP009832, 2008SP010385

Study: SWOG S0600
SAE Posted: 08-02-14322, 08-02-14660 FU1

Corrections to Previously Posted Documents

NCCTG-N0147

Amendment Review (AR) Addendum #9 Approval 08/01/08
Documents Posted:
Protocol Version Date 07/21/08

Correction:
Clean copy of protocol replaced version with tracked changes.

RTOG-0534

Continuing Review (CR) June 2008 Approval 06/06/08
Documents Posted:
Protocol Version Date 10/03/07

Correction:
Protocol Version Date 10/03/07 replaced in "Current Study Documents" category with Continuing Review June 2008 version.

SWOG-S0502

Amendment Review (AR) Revision #1 Approval 06/23/08
Documents Posted:

Informed Consent Document (Tissue Consent Supplement) for Protocol Version Date 04/24/08 [Per Rev1]

Correction:
Tissue Consent Supplement added per local site request.

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.