



NCI Central IRB Study Activity Update

March 31, 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-30610

Initial Review 2008 Approval

Documents Posted:

- Protocol Version 01/18/08
- Protocol Version 12/18/07
- Protocol Version 09/14/07
- Informed Consent for Protocol Version 01/18/08
- CIRB Initial Review Application Protocol Version 01/18/08
- CIRB Initial Review Application Protocol Version 12/18/07
- CIRB Initial Review Application Protocol Version 09/14/07
- 02/01/08: Reviewer 3 Comments (Pharmacist)
- 02/01/08: Reviewer 2 Comments
- 01/14/08: Reviewer 4 Comments
- 01/14/08: Reviewer 2 Comments
- 01/14/08: Reviewer 1 Comments
- 01/14/08: Reviewer 5 Comments
- 11/02/07: Reviewer 1 Comments
- 11/02/07: Reviewer 2 Comments
- 11/02/07: Reviewer 3 Comments (Pharmacist)
- 11/02/07: Reviewer 5 Comments
- 02/14/08: CIRB Initial Review Approval February 2008 (Protocol Version 01/18/07)
- 01/28/08: Group Response to CIRB
- 01/18/08: CIRB Tabled Response
- 12/18/07: Group Response to CIRB
- 11/28/07: CIRB Approval Pending Modification
- 10/03/07: CTEP Approval on Hold
- 09/14/07: Group Response - PIO
- 03/23/07: Group Response - PIO
- 02/01/08: CIRB Meeting Minutes
- 01/14/08: CIRB Meeting Minutes
- 11/02/07: CIRB Meeting Minutes



Pediatric CIRB Studies

COG – ACCL0631

Initial Review 2007 Approval
Documents Posted:

- Protocol Version Date 07/20/07
- Protocol Version Date 07/20/07 - Highlighted Version
- Protocol Version Date 01/30/07
- Protocol Version Date 01/30/07 - Highlighted Version
- CIRB Application (Protocol Version Date 07/20/07)
- CIRB Application (Protocol Version Date 01/30/07)
- 08/23/07: Primary Reviewer 1 Comments
- 05/10/07: Primary Reviewer 1 Comments
- 05/10/07: Primary Reviewer 2 Comments
- 05/10/07: Primary Reviewer 3 Comments
- 09/18/07: CIRB Final Approval (Protocol Version Date 07/20/07)
- 07/20/07: Group Response Letter
- 05/29/07: CIRB Table of Initial Review (Protocol Version Date 01/30/07)
- 01/30/07: Group Change Letter
- 08/23/07: Minutes - Group Response to Initial Tabled Review
- 05/10/07: Minutes - Initial Review

Other Activity Posted:

ACOSOG-Z1031

Continuing Review (CR) Continuing Review October 2007 Approval
Documents Posted:

- 10/04/07: Reviewer Comments

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

CALGB-40302

Continuing Review (CR) Continuing Review October 2007 Approval
Documents Posted:

- 10/04/07: Reviewer Comments

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



CALGB-90203

Amendment Review (AR): Update #2 (Protocol Version Date 02/12/08)
Documents Posted:

- Protocol Update Summary
- CIRB Amendment Review Application (Protocol Version 02/12/08)
- Summary of CIRB Application Revisions
- 02/25/08: CIRB Update 2 Approval February 2008 (Protocol Version 02/12/08)
- Protocol Version 02/12/08
- Informed Consent for Protocol Version 02/12/08 [per Up 2 Feb 08]

COG – AAML0431

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

- 02/14/08: Primary Reviewer 1 Comments
- 02/14/08: Minutes - Continuing Review

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

COG – AAML06P1

Continuing Review (CR): Continuing Review December 2007
Documents Posted:

- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Minutes - Continuing Review

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

COG – ACCL05C1

Amendment Review (AR): Amendment #1A (Protocol Version Date 02/20/08)
Documents Posted:

- CIRB Application (Protocol Version Date 02/20/08)
- 02/29/08: CIRB Approval Amendment #1A (Protocol Version Date 02/20/08)
- 02/20/08: Change Letter
- Protocol Version Date 02/20/08
- Protocol Version Date 02/20/08 - Highlighted Version
- Informed Consent Form for Protocol Version Date 02/20/08



Continuing Review (CR): December 2007
Documents Posted:

- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Minutes - Continuing Review

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

COG – ACCL0631

Amendment Review (AR): Amendment Approval (Protocol Version Date 02/07/08)
Documents Posted:

- CIRB Application (Protocol Version Date 02/07/08)
- 02/29/08: CIRB Approval Amendment (Protocol Version Date 02/07/08)
- 02/07/08: Change Letter
- Protocol Version Date 02/07/08
- Protocol Version Date 02/07/08 - Highlighted Version
- Informed Consent Form for Protocol Version Date 02/07/08

COG – ACNS0222

Continuing Review (CR): Continuing Review December 2007
Documents Posted:

- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Minutes - Continuing Review

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

COG – ACNC0232

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

- CIRB Continuing Review Application (Protocol Version Date 09/14/06)
- 03/24/08: CIRB Approval to Continuing Review March 2008 (Protocol Version Date 09/14/06)
- 01/07/08: CIRB: Continuing Review Reminder Notice
- Protocol Version Date 09/14/06
- Informed Consent Form for Protocol Version Date 09/14/06
- Study Committee Progress Report Dated 10/01/2007
- 10/25/07: DSMC Report



COG – ACNS0332

Continuing Review (CR): Continuing Review January 2008

Documents Posted:

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Minutes - Continuing Review

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

COG – AEWS0521

Amendment Review (AR): Activation Amendment (Protocol Version Date 01/31/08)

Documents Posted:

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Minutes - Amendment Review

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

COG – AEWS07B1

Continuing Review (CR): Continuing Review March 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/27/07)
- 03/24/08: CIRB Approval to Continuing Review March 2008 (Protocol Version Date 12/27/07)
- 02/13/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 12/27/07
- Informed Consent Form for Protocol Version Date 12/27/07 - Initial Diagnosis
- Informed Consent Form for Protocol Version Date 12/27/07 - Recurrence

COG – AGCT0521

Initial Review 2006

Documents Posted:

- 11/30/06: Primary Reviewer 1 Comments
- 11/30/06: Primary Reviewer 2 Comments
- 11/30/06: Primary Reviewer 3 Comments
- 11/30/06: Minutes - Initial Review

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



COG – ARAR0332

Continuing Review (CR): Continuing Review December 2007

Documents Posted:

- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Minutes - Continuing Review

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

COG – AREN03B2

Continuing Review (CR): Continuing Review January 2008

Documents Posted:

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Minutes - Continuing Review

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

COG – AREN0533

Continuing Review (CR): Continuing Review December 2007

Documents Posted:

- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Minutes - Continuing Review

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

COG – ARET0231

Continuing Review (CR): Continuing Review January 2008

Documents Posted:

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Minutes - Continuing Review

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

COG – ARST03P1

Continuing Review (CR): Continuing Review March 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/12/06)



- 03/24/08: CIRB Approval to Continuing Review March 2008 (Protocol Version Date 01/12/06)
- 02/13/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/12/06

COG – ARST0431

Amendment Review (AR): CIRB Acknowledgement of Study Closure Documents Posted:

- 03/17/08: Acknowledgement of Closure of Accrual for ARST0431 Study
- 03/07/08: Memo re Temporary Closure of Accrual for ARST0431 Study

COG – ASCT0431

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

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: 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-1A05

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

- CIRB Continuing Review Application (Protocol Version 06/25/07)
- 03/20/08: CIRB Continuing Review Approval 3/17/08 Protocol Version 06/25/07
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 06/25/07
- Informed Consent for Protocol Version 06/25/07 [per Mar 08 CR]
- 03/13/08: Reviewer Comments
- Study Summary - November 2007

ECOG-1A06

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

- CIRB Continuing Review Application (Protocol Version 08/31/07)
- 03/24/08: CIRB Continuing Review Approval 3/24/08 Protocol Version 08/31/07
- 01/10/08: CIRB Continuing Review Notice
- Protocol Version 08/31/07
- Informed Consent for Protocol Version 08/31/07 [per CR Mar 08]



ECOG-E1505

Amendment Review Addendum #5 Approval February 2008

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 02/12/08)
- Summary of CIRB Application Revisions (Protocol Version 02/12/08)
- CIRB Amendment Review Application (Protocol Version 11/09/07)
- Summary of CIRB Application Revisions (Protocol Version 11/09/07)
- 02/28/08: CIRB Approval Addendum 5 February 2008 Protocol Version 02/12/08
- 02/12/08: Group Response to CIRB
- 02/04/08: CIRB Approval Pending Modification
- 11/09/07: Group - CTEP Letter
- Protocol Version 02/12/08
- Protocol Version 11/09/07
- Informed Consent for Protocol Version 02/12/08 [per Add 5 Feb 08]
- 01/03/08: Reviewer Comments
- 01/04/08: CIRB Meeting Minutes

ECOG-E5103

Amendment Review Addendum #2 Approval February 2008

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 02/07/08)
- Summary of CIRB Application Revisions
- 02/28/08: CIRB Addendum 2 Approval February 2008 Protocol Version Date 02/07/08
- 02/07/08: Group-CTEP Letter
- Protocol Version 02/07/08
- Informed Consent for Protocol Version 02/07/08 [per Add #2 Feb 08]

GOG-0209

Continuing Review (CR) Continuing Review November 2007 Approval

Documents Posted:

- 11/14/07: Reviewer Comments

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



GOG-0218

Continuing Review (CR) Continuing Review November 2007 Approval
Documents Posted:

- 11/25/07: Reviewer Comments
- 11/18/07: Reviewer Comments

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

NCCTG-N0147

Amendment Review Addendum #7 Approval November 2007
Documents Posted:

- 11/25/07: Reviewer Comments
- 11/18/07: Reviewer Comments

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

NSABP-B-35

Continuing Review (CR) Continuing Review November 2007 Approval
Documents Posted:

- 11/14/07: Reviewer Comments

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

NSABP-B-40

Amendment Review Addendum #2 Approval March 2008
Documents Posted:

- Summary of Changes (Protocol Version 02/15/08)
- Summary of Changes (Protocol Version 11/15/07)
- CIRB Amendment Review Application (Protocol Version 02/15/08)
- Summary of CIRB Application Revisions (Protocol Version 02/15/08)
- CIRB Amendment Review Application (Protocol Version 11/15/07)
- Summary of CIRB Application Revisions (Protocol Version 11/15/07)
- 03/24/08: CIRB Amendment 2 Approval March 2008 (Protocol Version 02/15/08)
- 03/24/08: CIRB Acknowledgement of Receipt - Group Response
- 02/15/08: Group - CTEP Response
- 02/07/08: Group Response to CIRB
- 01/31/08: CIRB Approval with Recommendations



- 11/16/07: Group - CTEP Letter
- 11/14/07: Group - Principal Investigators Letter
- Protocol Version 02/15/08
- Protocol Version 11/15/07
- Informed Consent for Protocol Version 02/15/08 [per Am 2 Mar 08]
- 01/03/08: Reviewer Comment
- 01/04/08: CIRB Meeting Minutes

RTOG-0126

Continuing Review (CR) Continuing Review November 2007 Approval Documents Posted:

- 11/18/07: Reviewer Comments

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

RTOG-0415

Continuing Review (CR) Continuing Review October 2007 Approval Documents Posted:

- 10/04/07: Reviewer Comments

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

RTOG-0617

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

- CIRB Continuing Review Application (Protocol Version 8/1/07)
- 03/28/08: CIRB Continuing Review Approval March 2008 (Protocol Version 8/1/07)
- 03/26/08: Group - CIRB Response Letter
- 03/24/08: CIRB Approval Pending Modification
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 08/01/07
- Informed Consent for Protocol Version 08/01/07 [per CR Mar 08]
- Protocol Status Summary - January 2008
- 06/15/07: DMC Minutes



SWOG-0124

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

- CIRB Continuing Review Application (Protocol Version 06/29/07)
- 03/19/08: CIRB Continuing Review Approval 3/17/08 (Protocol Version 06/29/07)
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 06/29/07
- 03/15/08: Reviewer Comments
- 01/17/08: SAE Report
- 10/11/07: DSMC Memo
- May 2007 - Lung Committee

SWOG-S0221

Amendment Review Amendment #5 Approval February 2008
Documents Posted:

- CIRB Amendment Review Application (Protocol Version 01/01/08)
- Summary of CIRB Application Revisions
- 02/25/08: CIRB Amendment 5 Approval February 3008 (Protocol Version 01/01/08)
- Protocol Version 01/01/08
- Informed Consent for Protocol Version 01/01/08 [per Am 5 Feb 08]
- 02/21/08: Reviewer Comments
- 02/22/08: CIRB Meeting Minutes

SWOG-0421

Continuing Review (CR) Continuing Review November 2007 Approval
Documents Posted:

- 11/25/07: Reviewer Comments
- 11/16/07: Reviewer Comments

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



Serious Adverse Events

Study: ACOSOG-Z1031
SAE Posted: 1921886(2), 1134170, 1566999, 1432888, 1134170(1)

Study: CALGB 40503
SAE Posted: 248756(2)

Study: CALGB 80303
SAE Posted: 1696275, 248340, 250367(2), 248756(2)

Study: CALGB 90206
SAE Posted: 1696275, 248340, 250866(1), 250367(2), 248756(2)

Study: CALGB 90401
SAE Posted: 1696275, 248340, 250866(1), 250367(2), 248756(2)

Study: ECOG E1105
SAE Posted: 248340, 250866(1), 250367(2), 248756(2)

Study: ECOG E1305
SAE Posted: 250866(1), 248756(2)

Study: ECOG E1505
SAE Posted: 248340, 250866(1), 250367(2), 248756(2)

Study: ECOG E2100
SAE Posted: 250866(1), 248756(2)

Study: ECOG E2603
SAE Posted: 1396114

Study: ECOG E2805
SAE Posted: 1396114

Study: ECOG E4599
SAE Posted: 1696275, 250866(1), 250367(2), 248756(2)

Study: ECOG E5103
SAE Posted: 1696275, 248340, 250866(1), 250367(2), 248756(2)

Study: ECOG E5202
SAE Posted: 1696275, 248340, 250866(1), 250367(2), 248756(2)



Study: ECOG 5204

SAE Posted: 1696275, 248340, 250866(1), 250367(2), 248756(2)

Study: GOG 0213

SAE Posted: 1696275, 250866(1), 250367(2), 248756(2)

Study: GOG 0218

SAE Posted: 1696275, 248340, 250866(1), 250367(2), 248756(2)

Study: SWOG S0502

SAE Posted: 250367(2), 248756(2)

Study: SWOG S0518

SAE Posted: 1696275, 250866(1), 250367(2), 248756(2)

Study: SWOG S0600

SAE Posted: 1696275, 07-02-12974, 248340, 1896903, 1129949, 250866(1), 250367(2), 248756(2)

Study: NSABP B-38

SAE Posted: GB200711004216, JP200709000002(2)

Study: NSABP B-40

SAE Posted: 1696275, 248340, 250434(2), 250868(2), 252388(1), 252935, 250367(2), GB200711004216, JP200709000002(2), 248756(2), 250367(4), 250866(2), 252388(3), 252935(1), 250868(1)

Study: NSABP C-08

SAE Posted: 1696275, 250434(2), 250868(2), 252388(1), 252935, 250367(2), 248756(2), 250367(4), 250866(2), 252388(3), 252935(1)

Study: CALGB 80203

SAE Posted: 07-02-12974

Study: NCCTG 0147

SAE Posted: 07-02-12974, 07-02-13577, 07-02-13307(1)

Study: RTOG 0522



SAE Posted: 07-02-13577

Study: RTOG 0320

SAE Posted: 1396114, 248756(2), 2007SP012156(2)

Study: RTOG 0525

SAE Posted: 2007SP012156(2)

Study: NSABP-B34

SAE Posted: 200718095GPV Safety Update #66, 200715690NA Safety Update #67, 200716245NA Safety Update #68, 200711360BNE Safety Update #69(1), 200711360BNE Safety Update #69(2)

Corrections to Previous Study Activity Updates

ECOG-E2805

Continuing Review Approval August 2007

Documents Posted:

Informed Consent for Protocol Version 03/21/07 (per CR Aug 07)

Correction:

Informed Consent was revised to correct Header/Footer discrepancy.

NSABP-B-39-RTOG-0413

Continuing Review Approval February 2008

Documents Posted:

03/27/08: ERRATUM Letter (Protocol Version Error)

Correction:

The original outcome letter incorrectly listed the protocol version as 03/17/07. The correct protocol version is 03/13/07.

NSABP-R-04

Continuing Review Approval February 2008

Documents Posted:

Informed Consent (Tissue) for Protocol Version 06/12/07 [per Feb 08CR]

Main Informed Consent (Tissue) for Protocol Version 06/12/07 [per Feb 08CR]



Correction:

Both Informed Consents were revised to correct Header error.

SWOG-S0221

Amendment Review Amendment 5 Approval February 2008

Documents Posted:

02/22/08: CIRB Meeting Minutes

Correction:

Incorrect version of minutes was replaced with appropriate version.

SWOG-S0521

Amendment Review Revision 1 Approval December 2007

Documents Posted:

1. Activation Amendment (Protocol Version Date 04/18/07) [CTEP Version 4]
CTEP version 4.

2. Informed Consent for Protocol Version 09/21/07 (per Rev #1 Dec 07)

Correction:

1. Initial Amendment (Revision 4) title was changed to: Activation Amendment (Protocol Version Date 04/18/07) [CTEP Version 4]
2. Informed Consent for Revision #1 was replaced with revised edition to correct header discrepancy.

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.