



NCI Central IRB Study Activity Update January 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-10501

Initial Review 2008 Approval

Documents Posted:

- Protocol Version 06/14/07
- Protocol Version 04/09/07
- Protocol Version 01/17/07
- Protocol Version 11/27/06
- CIRB Review Application (Protocol Version 06/14/07)
- CIRB Review Application (Protocol Version 04/09/07)
- CIRB Review Application (Protocol Version 01/17/07)
- 06/26/07: CIRB Final Approval (Protocol Version 06/14/07)
- 06/14/07: Group Response Letter
- 06/05/07: CIRB Approval Pending Modification of Group Response (Protocol Version 04/09/07)
- 04/19/07: Group Response Letter
- 04/06/07: CIRB Approval Pending Modification (Protocol Version 01/17/07)
- 01/17/07: Group Response-Follow Up Review
- 01/17/07: CTEP Protocol Approval
- 12/12/06: CTEP Follow Up Review Letter
- 12/04/06: Group Response Letter
- 05/21/07: CIRB Meeting Minutes
- 03/19/07: CIRB Meeting Minutes
- CALGB: Hospital Anxiety and Depression Scale Form
- CALGB: EQ-5D Form
- CALGB: CLL Medication Sheet
- CALGB: Impact of Event Scale-Revised
- CALGB: Concerns About Cancer Progression

Amendment Review Amendment #2 Approval

Documents Posted:

- CIRB Review Application (Protocol Version 10/17/07)
- Summary of CIRB Application Revisions (Protocol Version 10/17/07)
- 12/12/07: CIRB Initial Review Approval December 2007 (Protocol Version Date 10/17/07)



- 10/17/07: Study Summary
- Protocol Version 10/17/07
- Informed Consent for Protocol Version 10/17/07 [per Amendment #2]

Pediatric CIRB Studies

COG – AAML05P1

Initial Review 2007

Documents Posted:

- Protocol Version Date 07/26/07
- Protocol Version Date 07/26/07 - Highlighted Version
- Protocol Version Date 05/07/07
- Protocol Version Date 05/07/07 - Highlighted Version
- Protocol Version Date 01/24/07
- Informed Consent Form for Protocol Version Date 07/26/07
- CIRB Application (Protocol Version Date 07/26/07)
- CIRB Application (Protocol Version Date 05/07/07)
- CIRB Application (Protocol Version Date 01/24/07)
- 06/14/07: Primary Reviewer 1 Comments
- 03/08/07: Primary Reviewer 1 Comments
- 03/08/07: Primary Reviewer 2 Comments
- 03/08/07: Primary Reviewer 3 Comments
- 09/18/07: CIRB Final Approval (Protocol Version Date 07/26/07)
- 07/26/07: Group Response Letter
- 06/25/07: CIRB Approval Pending Modification (Protocol Version Date 05/07/07)
- 05/07/07: Group Response Letter
- 04/17/07: CIRB Approval Pending Modification (Protocol Version Date 01/24/07)
- 06/14/07: Minutes - Group Response to Initial Review
- 03/08/07: Minutes - Initial Review

COG – ADVL0221

Initial Review 2005

Documents Posted:

- Protocol Version 06/28/05
- Protocol Version 06/28/05 (Track Changes)
- Protocol Version 05/13/05 (Track Changes)
- Protocol Version 01/05/05
- CIRB Application (Protocol Version 06/28/05)
- CIRB Application (Protocol Version 05/13/05)
- 08/16/05: CIRB Approval Version 06/28/05



- 08/09/05: CIRB Review of Response and Approval Protocol Version 06/28/05
- 07/15/05: Group Response Letter
- 05/31/05: CIRB Initial Review-Approval Pending Modification Protocol Version 01/05/05
- 05/13/05: Group Response Letter
- 03/07/05: CIRB Initial Review-Approval Pending Modifications Protocol Version 10/05/05
- 01/10/04: Group Change Memo
- Agent Request Form
- COG Group Shipment Request Form

Other Activity Posted:

ACOSOG-Z1031

Continuing Review (CR): October 2007
Documents Posted:

- 10/05/07: CIRB Meeting Minutes

ACOSOG-Z1041

Continuing Review: November 2007
Documents Posted:

- 11/02/07: CIRB Meeting Minutes

CALGB-10201

Continuing Review (CR): January 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/02/07)
- 1/13/08: CIRB Continuing Review Approval January 2008 (Protocol Version 05/02/07)
- Protocol Version 05/02/07 [per Jan 08 CR]
- Study Summary-June 2007

CALGB-40302

Continuing Review (CR): October 2007
Documents Posted:

- 10/05/07: CIRB Meeting Minutes



CALGB-90206

Amendment Review Update #9 Approval October 2007

Documents Posted:

- 10/05/07: CIRB Meeting Minutes

CALGB-140503

Continuing Review (CR): December 2007

Documents Posted:

- 12/07/07: CIRB Meeting Minutes

CALGB-70301

Continuing Review (CR): November 2007

Documents Posted:

- 11/19/07: CIRB Meeting Minutes

CALGB-SWOG-C80405

Continuing Review (CR): December 2007

Documents Posted:

- 12/07/07: CIRB Meeting Minutes

COG – AAML05P1

Continuing Review (CR): December 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/26/07)
- 01/02/08: CIRB Approval to Continuing Review December 2007 (Protocol Version Date 07/26/07)

COG – AAML0523

Continuing Review: November 2007

Documents Posted:

- 11/08/07: Primary Reviewer 1 Comments
- 11/08/07: Minutes - Continuing Review

COG – ADVL0221

Amendment Review (AR): Activation Amendment (Protocol Version Date 11/06/07)

Documents Posted:

- CIRB Application (Protocol Version Date 11/06/07)



- 12/11/07: CIRB Final Approval December 2007 (Protocol Version Date 11/06/07)
- 11/09/07: Group Change Letter
- Protocol Version Date 11/06/07
- Protocol Version Date 11/06/07 – Highlighted
- Informed Consent Form for Protocol Version Date 11/06/07

Amendment Review (AR): Amendment #1
Documents Posted:

- CIRB Application (Protocol Version Date 01/15/07)
- CIRB Application (Protocol Version Date 12/14/06)
- CIRB Application (Protocol Version Date 10/31/06)
- CIRB Application (Protocol Version Date 06/01/06)
- 01/25/07: CIRB Approval of Amendment #1 (Protocol Version Date 01/15/07)
- 01/11/07: CIRB Approval Pending Modification of Amendment #1 (Protocol Version Date 12/14/06)
- 12/11/06: CIRB Approval Pending Modification of Amendment 1 (Protocol Version Date 10/31/06)
- 10/31/06: Group Response Letter
- 07/24/06: Amendment Review - Tabled (Protocol Version Date 06/01/06)
- Protocol Version Date 01/15/07
- Protocol Version Date 01/15/07 - Highlighted Version
- Protocol Version Date 12/14/06
- Protocol Version Date 12/14/06 - Highlighted Version
- Protocol Version Date 10/31/06
- Protocol Version Date 10/31/06 - Highlighted Version
- Protocol Version Date 06/01/06
- Protocol Version Date 06/01/06 - Highlighted Version

COG – ADVL0221

Continuing Review (CR): January 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/06/07)
- 01/28/08: CIRB Approval to Continuing Review January 2008 (Protocol Version Date 11/06/07)
- Protocol Version Date 11/06/07
- Informed Consent Form for Protocol Version Date 11/06/07

Continuing Review (CR): April 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/15/07)



- 04/30/07: CIRB Approval to Continuing Review April 2007 (Protocol Version Date 01/15/07)

Continuing Review (CR): August 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/28/05)
- 08/22/06: CIRB Approval to Continuing Review August 2006 (Protocol Version Date 06/28/05)
- 06/27/06: CIRB Continuing Review Reminder Notice

Continuing Review (CR): November 2005

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/28/05)
- 11/23/05: CIRB Approval to Continuing Review November 2005 (Protocol Version Date 06/28/05)
- 10/05/05: CIRB Continuing Review Reminder Notice

COG – ANBL0531

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/12/07)
- 01/16/08: CIRB Approval to Continuing Review January 2008 (Protocol Version Date 09/12/07)
- Protocol Version Date 09/12/07
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment Group 2
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment Group 3
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment Group 4
- Informed Consent Form for Protocol Version Date 09/12/07 - Treatment for Residual or Recurrent, Localized Neuroblastoma

COG – ANBL0532

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application Protocol Version 05/29/07
- 01/28/08: CIRB Continuing Review Approval January 2008 (Protocol Version 05/29/07)
- 01/22/08: Group Response Letter
- Protocol Version 05/29/07



- Informed Consent (Induction Therapy Part 1) for Protocol Version 05/29/07
- Informed Consent (Therapy for High Risk Part 2) for Protocol Version 05/29/07

COG – AOST0331

Amendment Review (AR): CIRB Review of AOST0331 Investigators Brochure (April 2007)

Documents Posted:

- 05/09/07: AOST0331 Investigators Brochure Acknowledgement Memo

COG – AREN03B2

Continuing Review (CR): January 2008

Documents Posted:

- 01/28/08: CIRB Continuing Review Approval January 2008 (Protocol Version 03/20/07)
- 01/21/08: Group Response Letter
- Protocol Version 03/20/07
- Informed Consent Form for Protocol Version 03/20/07
- 10/25/07: DSMC Recommendation

COG – ARST0332

Initial Review 2006

Documents Posted:

- 12/08/05: Minutes - Initial Review

COG – ASCT0431

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/23/07)
- 01/16/08: CIRB Approval to Continuing Review January 2008 (Protocol Version Date 02/23/07)
- Protocol Version Date 02/23/07
- Informed Consent Form for Protocol Version Date 02/23/07
- 10/25/07: DSMC Report
- Study Committee Progress Report Dated 10/01/07

ECOG- E1899

Continuing Review (CR): October 2007

Documents Posted:

- 10/05/07: CIRB Meeting Minutes



ECOG-E2499

Amendment Review (AR): Addendum #6 Approval November 2006

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 06/15/06)
- Summary of CIRB Application Revisions
- 11/15/06: CIRB Addendum #6 Approval November 2006 (Protocol Version 06/15/06)
- 11/15/06: CTEP Approval as Written Letter
- 10/05/06: Group Response Letter
- 08/21/06: CIRB Approval Pending Modification (Protocol Version 06/15/06)
- 06/15/06: Group Response Letter
- Protocol Version 06/15/06

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application
- 01/22/08: CIRB Continuing Review Approval January 2008 (Protocol Version 06/15/06)
- Protocol Version 06/15/06

ECOG- E2902

Continuing Review (CR): December 2007

Documents Posted:

- 12/07/07: CIRB Meeting Minutes

Amendment Review (AR): Addendum #7 Approval December 2007

Documents Posted:

- CIRB Revision Application (Protocol Version 11/08/07)
- Summary of CIRB Application Revisions
- 12/26/07: CIRB Approval Addendum #7 December 2007 (Protocol Version 1/08/07)
- Protocol Version 11/08/07
- Informed Consent Form for Protocol Version 11/08/07 [per Add#7 Dec 07]



ECOG- E3201

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol version 03/07/07)
- 01/14/08: CIRB Continuing Review Approval January 2008 (Protocol Version 03/07/07)
- Protocol Version 03/07/07
- 04/18/06: DMC Minutes
- June-2006-Report of Studies

ECOG-E4402

Amendment Review Addendum #4 Approval December 2007

Documents Posted:

- CIRB Review Application (Protocol Version 08/24/07)
- Summary of CIRB Application Revisions (Protocol Version 08/24/07)
- CIRB Review Application (Protocol Version 06/01/07)
- 01/07/08: CIRB Addendum #4 Review Approval December 2007 (Protocol Version 08/24/07)
- 11/16/07: CIRB Group Response Approval (Protocol Version 08/24/07)
- 10/30/07: Group Response Letter
- 10/19/07: CIRB Response to E-Mail
- 10/08/07: CIRB Table of Group Response
- 07/17/07: CIRB Approval Pending Modification (Protocol Version 06/01/07)
- Protocol Version 08/24/07
- Protocol Version 06/01/07
- Informed Consent Form for Protocol Version 08/24/07 [per Add#4]
- 12/07/07: CIRB Meeting Minutes
- 09/17/07: CIRB Meeting Minutes
- 07/06/07: CIRB Meeting Minutes

GOG-0209

Continuing Review (CR): November 2007

Documents Posted:

- 11/19/07: CIRB Meeting Minutes

GOG-0212

Amendment Review Revision #4 Approval July 2007

Documents Posted:

- Appendix II Study Drug Distribution Procedures
- Appendix VIII Investigator Signature Page



GOG-0218

Continuing Review (CR): November 2007

Documents Posted:

- 11/26/07: Ad Hoc Meeting Minutes

GOG-0219

Continuing Review (CR): November 2007

Documents Posted:

- 11/02/07: CIRB Meeting Minutes

NCCTG-N0147

Amendment Review Addendum #7 Approval November 2007

Documents Posted:

- 11/26/07: Ad Hoc Meeting Minutes

NCCTG-N0574

Amendment Review Addendum #2 Approval October 2007

Documents Posted:

- 10/05/07: CIRB Meeting Minutes

NCIC CTG-PR.11

Continuing Review (CR): December 2007

Documents Posted:

- 12/07/07: CIRB Meeting Minutes

NSABP-B-34

Continuing Review (CR): November 2007

Documents Posted:

- 11/08/07: CIRB Ad Hoc Meeting Minutes

NSABP-B-35

Continuing Review (CR): November 2007

Documents Posted:

- 11/19/07: CIRB Meeting Minutes



NSABP-B-40

Continuing Review (CR): December 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/30/07)
- 01/07/08: CIRB Continuing Review Approval December 2007 (Protocol Version 05/30/07)
- 11/21/07: Group Review Letter
- Protocol Version 05/30/07
- Informed Consent for Protocol Version 05/30/07 [per Dec 07 CR]
- 12/17/07: CIRB Minutes
- 10/12/07: DMC Minutes
- 04/13/07: DMC Minutes
- Progress Report 2006

NSABP-B-42

Continuing Review (CR): November 2007

Documents Posted:

- 11/08/07: CIRB Ad Hoc Meeting Minutes

RTOG-0126

Continuing Review (CR): November 2007

Documents Posted:

- 11/19/07: CIRB Meeting Minutes

RTOG-0214

Continuing Review (CR): October 2007

Documents Posted:

- 10/15/07: CIRB Meeting Minutes

RTOG-0232

Continuing Review (CR): December 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/24/07)
- 01/07/08: CIRB Continuing Review Approval December 2007 (Protocol Version 01/24/07)
- Protocol Version 01/24/07
- Informed Consent for Protocol Version 01/24/07 [per Dec 07 CR]
- 12/07/07: CIRB Meeting Minutes



- 06/15/07: DMC Minutes
- June 2007: Report of Studies

RTOG-0415

Amendment Review Amendment #2 Approval December 2007

Documents Posted:

- Informed Consent (Tissue) for Protocol Version 12/03/07 [per Am 2 Dec 07]
- 11/08/07: CIRB Ad Hoc Meeting Minutes

RTOG-0425

Continuing Review (CR): October 2007

Documents Posted:

- 10/05/07: CIRB Meeting Minutes

SWOG-S0221

Continuing Review (CR): October 2007

Documents Posted:

- 10/15/07: CIRB Meeting Minutes

SWOG-S0226

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 11/13/06)
- 01/16/08: CIRB Continuing Review Approval January 2008 (Protocol Version 11/13/06)
- Protocol Version 11/13/06
- Informed Consent Form for Protocol Version 11/13/06 [per CR Jan 08]
- 11/26/07: SAE Report
- 10/11/07: DSMC Memo
- 06/01/07: DSMC Memo
- Report of Studies-Fall 2007

SWOG-S0421

Continuing Review (CR): November 2007

Documents Posted:

- 11/02/07: CIRB Meeting Minutes
- 11/26/07: Ad Hoc Meeting Minutes



SWOG-S0500

Continuing Review (CR): January 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/15/07)
- 01/22/08: CIRB Continuing Review Approval January 2008 (Protocol Version 05/15/07)
- 11/26/07: CIRB Continuing Review Notice
- Protocol Version 05/15/07
- Informed Consent for Protocol Version 05/15/07 [per CR Jan 08]
- 10/04/07: DSMC Minutes
- 10/4-10/7 2007: Report of Studies

SWOG-S9925

Amendment Review (AR): Revision #11 Approval October 2007

Documents Posted:

- CIRB Application Protocol Version 10/19/07
- Summary of CIRB Application Revisions
- 11/01/07: CIRB Amendment Revision#11 Approval (Protocol Version 10/19/07)
- Protocol Version 10/19/07

Serious Adverse Events

Study: NSABP-B-38
SAE Posted: JP200711001786

Study: NSABP-B-40
SAE Posted: JP200711001786

Study: NSABP-B-38
SAE Posted: AU200611001243 (1)

Study: NSABP-B-40
SAE Posted: AU200611001243 (1)

Study: NSABP-C-08
SAE Posted: 248750 (2)

Study: NSABP-B-40
SAE Posted: 248750 (2)

Study: NSABP-C-08
SAE Posted: 250367 (1)



Study: NSABP-B-40
SAE Posted: 250367 (1)

Study: NSABP-C-08
SAE Posted: 250434

Study: NSABP-B-40
SAE Posted: 250434

Study: NSABP-C-08
SAE Posted: 250868

Study: NSABP-B-40
SAE Posted: 250868

Study: RTOG 0320
SAE Posted: 2007SP020934 (1)

Study: RTOG 0525
SAE Posted: 2007SP020934 (1)

Study: RTOG 0320
SAE Posted: 2007SP020357 (2)

Study: RTOG 0525
SAE Posted: 2007SP020357 (2)

Study: RTOG 0320
SAE Posted: 2007SP014751 (4)

Study: RTOG 0525
SAE Posted: 2007SP014751 (4)

Study: RTOG 0320
SAE Posted: 2006-06-2337 (2)

Study: RTOG 0525
SAE Posted: 2006-06-2337 (2)

Study: CALGB 40302
SAE Posted: VEG 105281

Study: CALGB 90401
SAE Posted: 1476709



**Study: CALGB 90206
SAE Posted: 1476709**

**Study: CALGB 80303
SAE Posted: 1476709**

**Study: CALGB 80203
SAE Posted: 1476709**

**Study: ECOG 1505
SAE Posted: 1476709**

**Study: ECOG 5202
SAE Posted: 1476709**

**Study: ECOG 5204
SAE Posted: 1476709**

**Study: GOG 0218
SAE Posted: 1476709**

**Study: NCCTG 0147
SAE Posted: 1476709**

**Study: NSABP B-40
SAE Posted: 1476709**

**Study: NSABP R-04
SAE Posted: 1476709**

**Study: SWOG 0600
SAE Posted: 1476709**

**Study: CALGB 100104
SAE Posted: 1299978**

**Study: ECOG 1A05
SAE Posted: 1299978**

**Study: ECOG 1A05
SAE Posted: 163-C5013-07071689 (2)**

**Study: CALGB 100104
SAE Posted: 163-C5013-07071689 (2)**



**Study: ACOSOG-Z1031
SAE Posted: 1928987**

**Study: ACOSOG-Z1031
SAE Posted: 1108917**

**Study: RTOG 0320
SAE Posted: 2007SP007552 (6)**

**Study: RTOG 0525
SAE Posted: 2007SP007552 (6)**

**Study: RTOG 0320
SAE Posted: 2007SP020934**

**Study: RTOG 0525
SAE Posted: 2007SP020934**

**Study: NSABP B-40
SAE Posted: 246872**

**Study: NSABP B-40
SAE Posted: 246935**

**Study: NSABP B-40
SAE Posted: 247117**

**Study: NSABP B-40
SAE Posted: 247765**

**Study: NSABP B-40
SAE Posted: 247544**

**Study: NSABP B-40
SAE Posted: 247117 (2)**

**Study: NSABP B-40
SAE Posted: 246935 (1)**

**Study: NSABP B-40
SAE Posted: 246872 (1)**

**Study: NSABP B-40
SAE Posted: 246769 (1)**



Study: NSABP C-08
SAE Posted: 246769 (1)

Corrections to Previous Study Activity Updates

Study Number

Continuing Review (CR): December 2007

Documents Posted:

01/23/08: ERRATUM: CIRB CR Approval December 2007 (Protocol Version 06/13/07)

Correction: The CALGB/SWOG 80405 continuing review approval letter dated January 8, 2008 contains an error. The date of the meeting at which the study was reviewed was December 7, 2007 not December 7, 2008.

COG – ANBL0523

Continuing Review: November 2007

Documents Posted:

- 11/08/07: Primary Reviewer 1 Comments
- 11/08/07: Minutes - Continuing Review

Correction: Please disregard study ANBL0523 as this study is not an active CIRB study. The previous Study Activity Update Letter has now been corrected on the website

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.