



NCI Central IRB Study Activity Update

August 15, 2007

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

ACOSOG – Z1041

Initial Review 2006

Documents Posted:

- Protocol Version Date 01/09/07
- Protocol Version Date 01/09/07-Highlighted
- Protocol Version Date 08/22/06
- Protocol Version Date 08/22/06-Highlighted
- Informed Consent Form for Protocol Version Date 01/09/07
- CIRB Application (Protocol Version Date 01/09/07)
- CIRB Application (Protocol Version Date 08/22/06)
- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06: Primary Reviewer 2 Comments
- 02/28/07: Approval Letter
- 02/06/07: Resubmission Letter
- 12/28/06: CIRB Approval Pending Modification to Initial Review
- 08/22/06: Change Memo
- 12/01/06: Initial Review Meeting Minutes

Pediatric CIRB Studies

COG – ACNS0334

Initial Review 2005

Documents Posted:

- Protocol Version Date 04/10/06
- Protocol Version Date 04/10/06 Highlighted
- Protocol Version Date 01/04/06
- Protocol Version Date 01/04/06 Highlighted
- Protocol Version Date 08/24/05
- CIRB Application for Protocol Version Date 04/10/06
- CIRB Application Protocol Version Date 01/04/06
- CIRB Application Protocol Version Date 08/24/05
- 01/26/06: Primary Reviewer 1 Comments
- 01/26/06: Primary Reviewer 2 Comments
- 01/26/06: Primary Reviewer 3 Comments
- 10/06/05: Primary Reviewer 1 Comments
- 10/06/05: Primary Reviewer 2 Comments
- 10/06/05: Primary Reviewer 3 Comments



- 02/06/07: Group Response Letter
- 04/20/06: CIRB Final Approval of ACNS0334
- 04/14/06: Group Response Letter
- 01/04/06: Group Response Letter
- 08/24/05: Letter from the Group
- 01/11/05: CIRB Table of Initial Review
- 01/26/06: Initial Review

Other Activity Posted:

ACOSOG – Z1041

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

- CIRB Application (Protocol Version Date 05/23/07)
- 06/20/07: Approval Letter
- 05/23/07: Change Memo
- 04/19/07: Change Memo
- Protocol Version Date 05/23/07
- Informed Consent Form for Protocol Version Date 05/23/07

CALGB - 90401

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

- CIRB Continuing Review Application (Protocol Version Date 07/06/06)
- 08/07/07: Approval Letter
- Protocol Version Date 07/06/06
- Informed Consent Form for Protocol Version 07/06/06 [per CR Aug 07]
- Study Summary

Amendment Review (AR): Acknowledgment of Treatment Recommendations
Documents Posted:

- 08/01/07: CIRB Acknowledgement of Receipt
- 07/23/07: Treatment Recommendations

COG – ACNS0224

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

- CIRB Continuing Review Application Protocol Version Date 07/14/05
- 07/24/07: Full Board Approval Letter
- Informed Consent Form for Protocol Version Date 07/14/05 (Phase I)
- Informed Consent Form for Protocol Version Date 07/14/05 (Phase II)



- 04/20/07: DSMC Report
- 03/30/07: Study Committee Progress Report

COG – ACNS0334

Amendment Review (AR): Activation Amendment
Documents Posted:

- CIRB Application Protocol Version Date 06/15/07
- CIRB Application Protocol Version Date 01/22/07
- 07/24/07: CIRB Approval of ACNS0334 Activation Amendment
- 06/15/07: Group Response Letter
- 04/17/07: CIRB Full Board Approval Pending Modification
- Protocol Version Date 06/15/07
- Protocol Version Date 06/15/07 Highlighted
- Protocol Version Date 01/22/07
- Protocol Version Date 01/22/07 Highlighted
- Informed Consent Form for Protocol Version Date 06/15/07

COG – ACNS0334

Continuing Review (CR): November 2006 Approval
Documents Posted:

- 04/10/06: CIRB Application Protocol Version Date 04/10/06
- 11/27/06: CIRB Continuing Review Approval
- 09/20/06: CIRB Continuing Review Reminder Notice

COG – ANBL0322

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

- CIRB Continuing Review Application Protocol Version Date 05/22/06
- 07/25/07: Full Board Approval Letter
- 04/20/07: DSMC Report
- 03/30/07: Study Committee Progress Report Dated
- Informed Consent Form for Protocol Version Date 05/22/06

COG – ARST03P1

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

- CIRB Continuing Review Application for Protocol Version Date 01/12/06
- 07/05/07: Approval Letter



COG – D9902

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

- CIRB Continuing Review Application for Protocol Version Date 04/02/07
- 07/24/07: Full Board Approval Letter
- Informed Consent Form for Protocol Version Date 04/02/07

ECOG – E1505

Amendment Review (AR): Addendum #4
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 06/26/07)
- 07/16/07: Approval Letter
- 06/26/07: Letter from the Group
- Protocol Version Date 06/26/07
- Informed Consent Form for Protocol Version Date 06/26/07

ECOG – E1900

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

- CIRB Continuing Review Application (Protocol Version Date 12/30/04)
- 07/31/07: Approval Letter
- Protocol Version Date 12/30/04
- Informed Consent Form for Protocol Version Date 12/30/04 [per CR 07]
- 03/26/07 and 05/02/07: DMC Minutes
- Study Summary

GOG – 0198

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

- CIRB Continuing Review Application (Protocol Version Date 08/15/06)
- 07/17/07: Approval Letter
- Protocol Version Date 08/15/06
- Informed Consent Form for Protocol Version Date 08/15/06
[per CR July 07]
- Study Summary



RTOG - 0129

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

- CIRB Continuing Review Application (Protocol Version Date 01/31/05)
- 07/30/07: Approval Letter
- Protocol Version Date 01/31/05
- 06/15/07: DMC Minutes
- Study Summary

SWOG - S0106

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

- CIRB Continuing Review Application (Protocol Version Date 05/02/07)
- 07/25/07: Approval Letter
- Protocol Version Date 05/02/07
- Informed Consent Form for Protocol Version Date 05/02/07
[per CR July 07]
- Addendum B
- Addendum C
- Addendum D

SWOG - S0124

Amendment Review (AR): Amendment #3
Documents Posted:

- 07/13/07: Approval Letter
- Protocol Version Date 06/29/07

SWOG - S0309

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

- CIRB Continuing Review Application (Protocol Version Date 02/12/07)
- 07/23/07: Approval Letter
- Protocol Version Date 02/12/07
- Study Summary

SWOG - S0337

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

- CIRB Continuing Review Application (Protocol Version Date 05/01/07)
- 07/30/07: Approval Letter



- Protocol Version Date 05/01/07
- Informed Consent Form for Protocol Version Date 05/01/07 [per CR 07]

SWOG - 9007

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

- CIRB Continuing Review Application (Protocol Version Date 02/27/07)
- 07/24/07: Approval Letter
- Protocol Version Date 02/27/07
- Informed Consent Form for Protocol Version Date 02/27/07
[per CR July 07]

SWOG – S9910

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

- CIRB Continuing Review Application (Protocol Version Date 02/26/07)
- 07/24/07: Approval Letter
- Protocol Version Date 02/26/07
- Informed Consent Form for Protocol Version Date 02/26/07
[per CR July 07]
- Addendum B

Serious Adverse Events

Study: CALGB 80303
SAE Posted: 235918

Study: CALGB-SWOG 80405
SAE Posted: 235918

Study: CALGB 90206
SAE Posted: 235918

Study: CALGB 90401
SAE Posted: 235918

Study: ECOG E2100
SAE Posted: 235918

Study: ECOG E3200
SAE Posted: 235918



Study: ECOG E4599
SAE Posted: 235918

Study: ECOG E5202
SAE Posted: 235918

Study: ECOG E5204
SAE Posted: 235918

Study: GOG-0218
SAE Posted: 235918

Study: NSABP B-40
SAE's Posted: 231325 (3), 232048 (1), 235918, 236972 (1), 236972 (2), 240958, 240958 (1), 240959

Study: NSABP C-08
SAE's Posted: 231325 (3), 235918, 236972 (2)

Study: RTOG 0522
SAE Posted: DDL # 250 / 07-02-12102

Study: SWOG S0205
SAE Posted: DDL # 250 / 07-02-12102

Study: SWOG S0600
SAE Posted: DDL # 250 / 07-02-12102

Corrections to Previous Study Activity Updates

COG - ARST0431

Amendment Review (AR): Amendment #2
Documents Posted:

- 02/23/07: Approval Pending Modification (Protocol Version Date 02/23/07)

Correction: Updated Approval Pending Modification Letter corrected to Amendment #2 instead of Amendment #4.

If you have any questions about your local review process, please contact your Local IRB office.

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