



NCI Central IRB Study Activity Update September 14, 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

ECOG-E1A05

Initial Review 2007

Documents Posted:

- Protocol Version Date 06/25/07
- Protocol Version Date 12/20/06
- Informed Consent Form for Protocol Version Date 06/25/07
- Summary of CIRB Application Revisions (Protocol Version Date 06/25/07)
- CIRB Application (Protocol Version Date 06/25/07)
- CIRB Application (Protocol Version Date 04/11/07)
- CIRB Application (Protocol Version Date 12/20/06)
- 07/20/07: CIRB Final Approval
- 05/23/07: CIRB Approval Pending Modification of the Group Response to the Initial Review
- 04/11/07: Response to CIRB Review
- 03/21/07: CIRB Table of Initial Review
- 12/20/06: Letter from the Group
- 05/04/07: Minutes: Group Response to Initial Review
- 02/12/07: Minutes: Initial Review
- 02/02/07: Minutes: Initial Review

Pediatric CIRB Studies

COG – ADVLO525

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 02/12/07
- Protocol Version Date 02/12/07 Highlighted
- Protocol Version Date 11/29/06
- Protocol Version Date 11/29/06 Highlighted
- Protocol Version Date 09/01/06
- Protocol Version Date 09/01/06 Highlighted
- CIRB Initial Review Application Protocol Version Date 02/12/07
- CIRB Initial Review Application Protocol Version Date 11/29/06
- CIRB Initial Review Application Protocol Version Date 09/01/06
- 12/28/06: Primary Reviewer 1 Comments
- 10/12/06: Primary Reviewer 1 Comments
- 10/12/06: Primary Reviewer 2 Comments



- 10/12/06: Primary Reviewer 3 Comments
- 10/12/06: Pharmacist Comments
- 02/20/07: CIRB Approval Letter
- 02/12/07: Group Response Letter
- 01/30/07: Group Response to Approval Pending Modification
- 11/29/06: Group Response Letter
- 10/20/06: CIRB Approval Pending Modification to Initial Review
- 09/01/06: Response Letter
- 12/28/06: Group Response to Initial Review
- 10/12/06: Initial Review

Other Activity Posted:

COG – ADVLO525

Continuing Review (CR): July 2007 Approval

Documents Posted:

- CIRB Continuing Review Application Protocol Version Date 02/12/07
- 07/31/07: CIRB Approval to Continuing Review July 2007 (Protocol Version Date 02/12/07)
- Informed Consent Form for Protocol Version Date 02/12/07

COG – AHOD03P1

Continuing Review (CR): August 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/08/05)
- 08/29/07: CIRB Approval to Continuing Review August 2007 (Protocol Version Date 20/08/05)
- Protocol Version Date 12/08/05
- Informed Consent Form for Protocol Version Date 12/08/05 [Per Aug. 07 CR]
- 04/17/07: DSMC Report
- Study Progress Report Dated 03/30/07

COG – ANHL04B1

Amendment Review (AR): Amendment #3

Documents Posted:

- CIRB Continuing Review Application Protocol Version Date 08/03/07
- 08/17/07: CIRB Approval to Continuing Review July 2007 (Protocol Version Date 08/03/07)
- 08/03/07: Group Response Change Memo
- Protocol Version Date 08/03/07
- Protocol Version Date 08/03/07 Highlighted



- Informed Consent Form for Protocol Version Date 08/03/07

ECOG – E1302

Continuing Review (CR): July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/29/06)
- 07/25/07: Approval Letter
- Protocol Version Date 11/29/06
- Informed Consent Form for Protocol Version Date 11/29/06
[per July 07 CR]
- 07/16/07: Minutes: Continuing Review
- DMC Minutes
- AE Report
- Study Summary & Toxicity Report

Amendment Review (AR): Addendum #7

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 06/06/07)
- 07/17/07: Approval Letter
- Protocol Version Date 06/06/07
- Informed Consent Form for Protocol Version Date 06/06/07
- 07/06/07: Minutes: Amendment Review

ECOG – E2805

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/21/07)
- 08/14/07: Approval Letter
- Protocol Version Date 03/21/07
- Informed Consent Form for Protocol Version Date 03/21/07
[per CR Aug 07]
- DMC Minutes
- 08/03/07: Minutes: Continuing Review
- Study Summary
- AE Report

ECOG – E4599

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/19/07)



- 09/05/07: Approval Letter
- Protocol Version Date 01/19/07
- Article from The New England Journal of Medicine
- Study Summary

ECOG – E5204

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/06/07)
- 09/05/07: Approval Letter
- Protocol Version Date 06/06/07
- Informed Consent Form for Protocol Version Date 06/06/07
[per CR Aug 07]
- DMC Minutes
- Study Summary

GOG – 0212

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/14/06)
- 09/04/07: Approval Letter
- Protocol Version Date 09/14/06
- Informed Consent Form for Protocol Version Date 09/14/06
[per CR Aug 07]
- DSMB Minutes
- 08/03/07: Minutes: Continuing Review
- Study Summary
- Appendix I
- Appendix II
- Appendix III
- Appendix IV
- Appendix V
- Appendix VI
- Appendix VII
- Appendix VIII
- Appendix IX
- Appendix X

Amendment Review (AR): Revision #4

Documents Posted:

- Summary of CIRB Application Revisions (Protocol Version Date 04/05/07)
- CIRB Application (Protocol Version Date 07/13/07)



- CIRB Application (Protocol Version Date 04/05/07)
- 07/16/07: Approval Letter
- 07/02/07: CIRB Approval Pending Modification
- 06/07/07: Response from the Group
- 06/05/07: CIRB Approval Pending Modification-Full Board
- 04/05/07: Amendment Request Letter
- Protocol Version Date 07/13/07
- Protocol Version Date 07/13/07 - Tracked Changes
- Protocol Version Date 04/05/07
- Informed Consent Form for Protocol Version Date 07/13/07
- 05/21/07: Minutes: Amendment Review

NCCTG – N0147

Continuing Review (CR): July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/28/05)
- 07/27/07: Approval Letter
- Informed Consent Form for Protocol Version Date 06/28/05
- 07/06/07: Minutes: Continuing Review
- NCCTG Data Monitoring Committee excerpt
- NCCTG Status Report for Study N0147 - April 2007

NCIC CTG – MA.27B

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/22/07)
- 08/09/07: Approval Letter
- Protocol Version Date 05/22/07
- Informed Consent Form for Protocol Version Date 05/22/07
[per CR Aug 07]
- DSMC Summary Report
- 08/03/07: Minutes: Continuing Review
- Study Summary
- Summary of Changes

NSABP – C - 09

Amendment Review (AR): Amendment #1

Documents Posted:

- Summary of Protocol and Consent Form Changes
- CIRB Application (Protocol Version Date 04/09/07)
- 06/05/07: Approval Letter
- 04/11/07: Letter from the Group



- Protocol Version Date 04/09/07
- Informed Consent Form for Protocol Version Date 04/09/07
- 05/21/07: Minutes: Amendment Review

Amendment Review (AR): Amendment #2

Documents Posted:

- Summary of CIRB Application Revisions
- Summary of Protocol Changes
- CIRB Application (Protocol Version Date 06/14/07)
- 07/30/07: Approval Letter
- Protocol Version Date 06/14/07
- Informed Consent Form for Protocol Version Date 06/14/07

RTOG – S0525

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/16/07)
- 09/04/07: Approval Letter
- Protocol Version Date 05/16/07
- Informed Consent Form for Protocol Version Date 05/16/07
[per CR Aug 07]
- 08/03/07: Minutes: Continuing Review
- Toxicity Report
- DMC Minutes

SWOG – S0012

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/02/07)
- 08/30/07: Approval Letter
- Protocol Version Date 02/02/07
- Study Summary

SWOG – S0200

Amendment Review (AR): Amendment #1

Documents Posted:

- 06/26/07: Approval Letter
- Protocol Version Date 06/11/07



SWOG – S0521

Continuing Review (CR): August 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/18/07)
- 08/30/07: Approval Letter
- Protocol Version Date 04/18/07
- Informed Consent Form for Protocol Version Date 04/18/07
[per CR Aug 07]

Serious Adverse Events

Study: ACOSOG-Z0131

SAE Posted: ACOSOG-Z0131_1258923 (1)

Study: CALGB 90202

SAE Posted: PHHO2007DE09444

Study: NCIC CTG MA.27

SAE Posted: 10000236

Study: NSABP B-40

SAE Posted: 242285, 242285 (1), 242575, 242575 (1), 243768

Study: NSABP C-08

SAE Posted: 240958 (1)

Study: RTOG 0522

SAE Posted: DDL # 246 (1) / 07-02-11278, DDL # 251 / 07-02-12107

Study: SWOG S0205

SAE Posted: DDL # 246 (1) / 07-02-11278

Study: SWOG S0600

SAE Posted: DDL # 246 (1) / 07-02-11278

Corrections to Previous Study Activity Updates

COG – ADVL0524

Amendment Review: Amendment #3

Correction: The ADVL0524 Amendment #3 was posted in April 2007 but it was not included in the April 15, 2007 Study Activity Update.



COG – ACNS0334

Amendment Review: Amendment #1

Correction: The ACNS0334 approval letter and consent form for Protocol Version Date 06/15/07 contain an error in the expiration date. The date should read "November 21, 2007" instead of "July 11, 2008." The approval letter, consent form and website have been corrected to reflect the November 21, 2007 expiration date.

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.