



NCI Central IRB Study Activity Update June 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

ECOG-E1505

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 02/08/06
- Protocol Version Date 12/20/05
- Informed Consent Form for Protocol Version Date 02/08/06
- CIRB Application (Protocol Version Date 12/20/05)
- 02/13/06: CIRB Final Approval
- 02/08/06: Group Response Letter
- 01/26/06: CIRB Approval Pending Modification to Initial Review
- 01/23/06: Minutes: Initial Review

SWOG – S0521

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 02/12/07
- Protocol Version Date 10/25/06
- Protocol Version Date 04/18/06
- CIRB Application (Protocol Version Date 02/12/07)
- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 04/18/06)
- 11/20/06: Primary Reviewer 1 Comments
- 11/20/06: Primary Reviewer 2 Comments
- 06/02/06: Primary Reviewer 1 Comments
- 06/02/06: Primary Reviewer 2 Comments
- 04/06/07: CIRB Final Approval of Group Response
- 02/12/07: Group Response Letter
- 01/22/07: CIRB Approval Pending Modification
- 06/16/06: Tabled Letter
- 03/19/07: Minutes: Group Response to Initial Review
- 11/20/06: Minutes: Initial Review - Group Response to Tabled Action
- 06/02/06: Minutes: Initial Review



Pediatric CIRB Studies

COG-ACNS-0222

Initial Review 2006

Documents Posted:

- Protocol Version Date 06/28/06 - Group Response
- Protocol Version Date 06/28/06 Highlighted Version - Group Response
- Protocol Version Date 01/25/06
- CIRB Application Protocol Version Date 06/28/06
- CIRB Application Protocol Version Date 01/25/06
- 04/24/06: Pharmacist Comments
- 04/24/06: Primary Reviewer 1 Comments
- 04/24/06: Primary Reviewer 2 Comments
- 04/24/06: Primary Reviewer 3 Comments
- 07/11/06: Approval Letter
- 07/11/06: Approval Letter Study Chair
- 06/28/06: Response Letter
- 05/02/06: Signed Initial Review APM Letter
- 04/24/06: Full Board Meeting Minutes

COG-AAML06P1

Initial Review 2006

Documents Posted:

- Protocol Version Date 02/26/07
- Protocol Version Date 02/26/07 Highlighted
- Protocol Version 01/19/07 Group Response
- Protocol Version 01/19/07 Highlighted Group Response
- Protocol Version Date 10/26/06
- Protocol Version Date 10/26/06 Highlighted
- Informed Consent Protocol Version Date 02/26/07
- CIRB Application Protocol Version Date 02/26/07
- CIRB Application Protocol Version Date 01/19/07
- CIRB Application Protocol Version Date 10/26/06
- 12/14/06: Pharmacist Comments
- 12/14/06: Primary Reviewer 1 Comments
- 12/14/06: Primary Reviewer 2 Comments
- 12/14/06: Primary Reviewer 3 Comments
- 03/29/07: Final Approval
- 02/26/07: Response Letter
- 02/26/07: CIRB Approval Pending Modification
- 01/19/07: Response Letter



- 01/02/07: Initial Review Tabled Study Chair
- 02/08/07: Group Response Initial Review Meeting Minutes
- 12/14/06: Initial Review Meeting Minutes

Other Activity Posted:

COG-ACNS-0222

Amendment Review (AA): Activation Amendment Protocol Version Date 05/08/07
Documents Posted:

- 04/06/07: CIRB Acknowledgement of Activation
- CIRB Application Protocol Version Date 05/08/07
- CIRB Application Protocol Version Date 02/07/07
- 05/24/07: Amendment Approval Letter
- 05/08/07: Response Letter
- 04/30/07: Full Board Amendment APM Letter
- 02/07/07: Revised Activation Amendment
- Protocol Version Date 05/08/07
- Protocol Version Date 05/08/07 Highlighted - Group Response
- Protocol Version Date 02/07/07
- Protocol Version Date 02/07/07 – Highlighted
- Informed Consent Protocol Version Date 05/08/07
- 04/12/07: Full Board Meeting Minutes

Continuing Review (CR) April 2006
Documents Posted:

- CIRB Application Protocol Version Date 06/28/06
- 03/12/07: Approval for Continuation Letter
- 12/01/06: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/28/06
- Informed Consent Protocol Version Date 06/28/06

COG- ACNS0332

Amendment Review (AA): Amendment #2 Protocol Version Date 03/28/07
Documents Posted:

- CIRB Application (Protocol Version Date 03/28/07)
- CIRB Application (Protocol Version Date 01/17/07)
- 05/22/07: Approval Letter (Protocol Version Date 03/28/07)
- 03/28/07: Response Memorandum



- 03/20/07: Approval Pending Modification (Protocol Version Date 01/17/07)
- 01/17/07: Change Memo
- Protocol Version Date 03/28/07
- Protocol Version Date 03/28/07, Highlighted Changes
- Protocol Version Date 01/17/07
- Protocol Version Date 01/17/07, Highlighted Changes
- Informed Consent Document Protocol Version Date 03/28/07

COG-ACNS0232

Continuing Review (CR) May 2007

Documents Posted:

- 05/24/07: CIRB Full Board Approval
- Informed Consent Protocol Version Date 09/14/06

ECOG – E1A00

Amendment Review (AR): Update #1 (Protocol Version Date 05/30/07)

Documents Posted:

- 06/11/07: Approval Letter
- Protocol Version Date 05/30/07

ECOG – E1302

Adverse Event Report (Protocol Version Date 11/29/06)

Documents Posted:

- 06/11/07: CIRB Acknowledgement of Review of an Adverse Event
- 02/12/07: Action Letter

ECOG – E1505

Amendment Review (AR): Addendum #3 (Protocol Version Date 04/17/07)

Documents Posted:

- CIRB Application (Protocol Version Date 03/05/07)
- 04/20/07: Approval Letter
- 04/17/07: Group Response Letter
- 04/17/07: CIRB Approval Pending Modification
- 03/05/07: Group Response Letter
- Protocol Version Date 04/17/07
- Protocol Version Date 03/05/07
- Informed Consent Form for Protocol Version Date 04/17/07
- 04/06/07: Minutes: Amendment Review



Amendment Review (AR): Addendum #2 (Protocol Version Date 07/28/06)
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 07/28/06)
- 09/27/06: Approval Letter
- 07/28/06: Group Response Letter
- Protocol Version Date 07/28/06
- Informed Consent Form for Protocol Version Date 07/28/06
- 09/01/06: Primary Reviewer 1 Comments

Amendment Review (AR): Addendum #1 (Protocol Version Date 06/23/06)
Documents Posted:

- Summary of CIRB Application Revisions (Protocol Version Date 06/23/06)
- CIRB Application (Protocol Version Date 06/23/06)
- 07/18/06: Approval Letter
- 06/23/06: Group Response Letter
- 06/12/06: CIRB Approval Pending Modification
- 04/25/06: Group Response Letter
- Protocol Version Date 06/23/06
- 06/02/06 Primary Reviewer 1 Comments
- 06/02/06: Minutes: Amendment Review

Continuing Review (CR) December 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/28/06)
- 12/28/06: Approval Letter
- 09/11/06: Continuing Review Notice Letter
- Protocol Version Date 07/28/06
- Informed Consent Form for Protocol Version Date 07/28/06

ECOG – E2100

Amendment Review (AR): Update #1 (Protocol Version Date 05/30/07)
Documents Posted:

- 06/11/07: Approval Letter
- Protocol Version Date 05/30/07



ECOG-E2603

Continuing Review (CR) June 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version date 01/31/07)
- 06/05/07: Approval Letter
- Protocol Version Date 01/31/07
- Informed Consent Form for Protocol Version Date 01/31/07
[per CR June 07]
- Serious Adverse Events
- Toxicity Summary

ECOG – E3805

Review of Recruitment Material (Frequently Asked Questions)

Documents Posted:

- Frequently Asked Questions
- Frequently Asked Questions - Revised
- 04/23/07: CIRB Approval of the Frequently Asked Question (FAQ)
- 04/06/07: CIRB Approval Pending Modification of the Recruitment Materials
- 03/19/07: Minutes: Recruitment Material Review

ECOG – E4A03

Amendment Review (AR): Update #1 (Protocol Version Date 01/24/07)

Documents Posted:

- CIRB Application (Protocol Version Date 01/24/07)
- 06/05/07: Approval Letter
- Protocol Version Date 01/24/07

Closure Notice Receipt

- 06/11/07: CIRB Acknowledgement of Receipt

NCCTG – N0434 (MA.27D)

Continuing Review (CR) June 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/28/06)
- 06/05/07: Approval Letter
- Protocol Version 06/28/06
- Informed Consent Form for Protocol Version Date 06/28/06
[per CR June 07]



ECOG – E4402

Continuing Review (CR) November 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/25/05)

RTOG - 0320

Amendment Review (AR): Amendment #4 (Protocol Version Date 05/08/07)
Documents Posted:

- CIRB Application Change Summary
- Summary of Protocol Changes
- CIRB Application (Protocol Version Date 05/08/07)
- 05/14/07: Approval Letter
- 05/03/07: CIRB Approval Pending Modification
- Protocol Version Date 05/08/07
- Protocol Version Date 05/08/07 - Tracked
- Protocol Version Date 02/27/07
- Informed Consent Form for Protocol Version Date 05/08/07
- 04/06/07: Minutes: Amendment Review

SWOG – S0124

Adverse Event #2006097842 (Protocol Version Date 01/16/07)
Documents Posted:

- 06/11/07: AE #2006097842 Follow-up 1

SWOG – S0307

Continuing Review (CR) June 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/25/07)
- 06/06/07: Approval Letter
- Protocol Version Date 01/25/07
- Informed Consent Form for Protocol Version Date 01/25/07
[per CR June 07]
- 05/09/07: DMC Minutes
- 10/19/06: DMC Minutes
- Serious Adverse Events
- Toxicity Summary



SWOG – S0427

Amendment Review (AR): Revision #3 (Protocol Version Date 03/02/07)
Documents Posted:

- 05/24/07: Approval Letter
- Protocol Version Date 03/02/07

SWOG – S0521

Amendment Review (AR): Revision #4 (Protocol Version Date 04/18/07)
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 04/18/07)
- 05/22/07: Approval Letter
- 04/18/07: Group Letter
- Protocol Version Date 04/18/07
- Informed Consent Form for Protocol Version Date 04/18/07

SWOG – S9910

Amendment Review (AR): Revision #13 (Protocol Version Date 02/26/07)
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 02/26/07)
- 05/23/07: Approval Letter
- Protocol Version Date 02/26/07
- Informed Consent Form for Protocol Version Date 02/26/07

Serious Adverse Events

Study: CALGB-80303
SAE Posted: 1880188

Study: CALGB-90206
SAE Posted: 1880188

Study: CALGB-90401
SAE Posted: 1880188

Study: CALGB-SWOG-80405
SAE Posted: 1880188

Study: ECOG E2100
SAE Posted: 1880188



Study: ECOG E2499
SAE Posted: ZD1839 (IND 61187) Investigator Notification
Study: ECOG E3200
SAE Posted: 1880188

Study: ECOG E4402
SAE Posted: ZD1839 (IND 61187) Investigator Notification

Study: ECOG E4599
SAE Posted: 1880188

Study: ECOG E5202
SAE Posted: 1880188

Study: ECOG E5204
SAE Posted: 1880188

Study: GOG-0218
SAE Posted: 1880188

Study: NSABP B-34
SAE Posted: DE-2006-032513 / Safety Update # 41 (2), FR-2006-031029 / Safety Update # 36 (1), GB-2007-010897 / Safety Update # 45

Study: NSABP B-38
SAE Posted: AU200703004434, DE200607005155 (2), DE200703003322, GB200704000162, GB200702004646 (1)

Study: NSABP B-40
SAE Posted: AU200703004434, DE200607005155 (2), DE200703003322, GB200704000162, GB200702004646 (1)

Study: NSABP C-08
SAE Posted: 1880188

Study: SWOG S0303
SAE Posted: 1880188

Study: SWOG S0307
SAE Posted: DE-2006-032513 / Safety Update # 41 (1), DE-2006-032513 / Safety Update # 41 (2), FR-2006-031029 / Safety Update # 36 (1), Safety Update # 37 (FU 1) / GB-2006-032523, GB-2006-040116 / Safety Update # 39 (1), GB-2006-040116 / Safety Update # 39 (2), GB-2007-010897 / Safety Update # 45, TR-2007-006800 / Safety Update # 44



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.