



NCI Central IRB Study Activity Update

April 30, 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.

Pediatric CIRB Studies

COG – ARET0231

Initial Review 2005 Approval

Documents Posted:

- Protocol Version Date 04/11/06
- Protocol Version Date 04/11/06, Highlighted
- Protocol Version Date 12/01/05
- Protocol Version Date 12/01/05, Highlighted
- Protocol Version Date 08/16/05
- Informed Consent Form for Protocol Version Date 04/11/06
- CIRB Application - revised (Protocol Version Date 04/11/06)
- CIRB Application (Protocol Version Date 12/01/05)
- CIRB Application (Protocol Version Date 08/16/05)
- CIRB Application - revised (Protocol Version Date 08/16/05)
- CIRB Application - Tracked Changes (Protocol Version Date 08/16/05)
- 03/09/06: Primary Reviewer 1 Comments
- 03/09/06: Primary Reviewer 2 Comments
- 03/09/06: 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
- 10/06/05: Pharmacist Comments
- 04/13/06: CIRB Final Approval
- 04/11/06: CIRB Response Letter
- 03/13/06: CIRB APM to Group Response
- 02/10/06: CIRB Response Letter
- 10/26/05: CIRB APM to Initial Review
- 08/16/05: Change Memo
- 03/09/06: Group Response Meeting Minutes
- 10/06/05: Initial Review Meeting Minutes

Other Activity Posted:

CALGB-30102

Continuing Review (CR) April 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/07/03)
- 04/19/07: Approval Letter



- Protocol Version 08/07/03
- Study Summary

CALGB-49907

Amendment Review (AR): Update #15 (Protocol Version Date 01/31/07)

Documents Posted:

- Summary of Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 01/31/07

CALGB-70301

Amendment Review (AR): Update #3 (Protocol Version Date 01/24/07)

Documents Posted:

- 03/15/07: Change Memo
- CIRB Application (Protocol Version Date 01/24/07)
- Summary of CIRB Application Revisions
- 03/27/07: Approval Letter
- Protocol Version Date 01/24/07
- Informed Consent Form for Protocol Version Date 01/24/07

CALGB-80101

Amendment Review (AR): Update #5 (Protocol Version Date 01/22/07)

Documents Posted:

- Summary of Revisions
- CIRB Application (Protocol Version Date 01/22/07)
- Summary of CIRB Application Revisions
- 03/27/07: Approval Letter
- Protocol Version Date 01/22/07
- Informed Consent Form for Protocol Version Date 01/22/07

CALGB-90202

Amendment Review (AR): Update #6 (Protocol Version Date 02/02/07)

Documents Posted:

- 04/15/07: Change Memo
- CIRB Application (Protocol Version Date 02/02/07)
- Summary of CIRB Application Revisions
- 03/23/07: Approval Letter
- Protocol Version Date 02/02/07
- Informed Consent Form for Protocol Version Date 02/02/07



COG – AAML0523

Amendment Review (AR): Amendment #2 (Protocol Version Date 01/12/07)
Documents Posted:

- 03/02/07: Approval Letter

COG – ACNS0332

Continuing Review (CR) March 2007 Approval
Documents Posted:

- CIRB Continuing Review Application for Protocol Version: 02/15/07
- 04/17/07: CIRB Approval Letter (Protocol Version Date: 02/15/07)
- Protocol Version Date 02/15/07
- Informed Consent for Protocol Version 02/15/07

COG – ARET0231

Amendment Review (AR): Activation Amendment (Protocol Version Date
03/03/07)
Documents Posted:

- CIRB Application (Protocol Version Date 03/03/07)
- 04/04/07: Approval Letter
- 03/03/07: Revisions to the Protocol
- Protocol Version Date 03/03/07
- Protocol Version Date 03/03/07, Highlighted
- Informed Consent Form for Protocol Version Date 03/03/07

Study Activation Notification:
Documents Posted:

- 04/16/07: Study Activation Letter

Continuing Review (CR) June 2006 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/11/06)
- 06/29/06: Approval Letter
- Protocol Version Date 04/11/06
- Protocol Version Date 04/11/06, Highlighted
- Informed Consent Form for Protocol Version Date 04/11/06



ECOG-E2603

Amendment Review (AR): Addendum #8 (Protocol Version Date 11/21/06)
Documents Posted:

- CIRB Application (Protocol Version Date 11/21/06)
- Summary of CIRB Application Revisions
- 01/24/07: Approval Letter
- 11/21/06: Group Letter
- Protocol Version Date 11/21/06
- Informed Consent Form for Protocol Version Date 11/21/06

Amendment Review (AR): Update #2 (Protocol Version Date 01/31/07)
Documents Posted:

- CIRB Application (Protocol Version Date 01/31/07)
- Summary of CIRB Application Revisions
- 03/27/07: Approval Letter
- Protocol Version Date 01/31/07
- Informed Consent Form for Protocol Version Date 01/31/07

ECOG-E2805

Amendment Review (AR): Update #2 (Protocol Version Date 03/21/07)
Documents Posted:

- CIRB Application (Protocol Version Date 03/21/07)
- Summary of CIRB Application Revisions
- 04/20/07: Approval Letter
- Protocol Version Date 03/21/07
- Informed Consent Form for Protocol Version Date 03/21/07

ECOG-E2902

Continuing Review (CR) February 2007 Approval
Documents Posted:

- 09/08/06: DMC Minutes
- Toxicity Summary
- 01/04/07: CIRB ADEERS Listing

ECOG-E5202

Amendment Review (AR): Update #1 (Protocol Version Date 03/07/07)
Documents Posted:

- CIRB Application (Protocol Version Date 03/07/07)
- Summary of CIRB Application Revisions
- 03/27/07: Approval Letter



- 03/07/07: Group Letter
- Protocol Version Date 03/07/07
- Informed Consent Form for Protocol Version Date 03/07/07

ECOG-E5204

Amendment Review (AR): Update #1 (Protocol Version Date 03/07/07)
Documents Posted:

- CIRB Application (Protocol Version Date 03/07/07)
- Summary of CIRB Application Revisions
- 03/27/07: Approval Letter
- 03/07/07: Group response
- Protocol Version Date 03/07/07
- Informed Consent Form for Protocol Version Date 03/07/07

ECOG-E6201

Amendment Review (AR): Update #1 (Protocol Version Date 03/07/07)
Documents Posted:

- 03/07/07: Study Updates
- Protocol Version Date 03/07/07

GOG-0209

Amendment Review (AR): Revision #9 (Protocol Version Date 12/18/06)
Documents Posted:

- 12/18/06: Change Memo
- CIRB Application (Protocol Version Date 12/18/06)
- Summary of CIRB Application Revisions
- 03/01/07: Approval Letter
- Protocol Version Date 12/18/06
- Appendix I
- Appendix II
- Appendix III
- Informed Consent Form for Protocol Version Date 12/18/06

GOG-0219

Amendment Review (AR): Revision #4 (Protocol Version Date 11/20/06)
Documents Posted:

- CIRB Application (Protocol Version Date 11/20/06)
- Summary of CIRB Application Revisions
- 01/24/07: Approval Letter
- 11/20/06: Summary of Changes
- Protocol Version Date 11/20/06



- Appendix I - per Revision #4
- Appendix II - per Revision #4
- Appendix III - per Revision #4
- Appendix IV - per Revision #4
- Appendix V - per Revision #4
- Appendix VI - per Revision #4
- Appendix VII - per Revision #4
- Appendix VIII - per Revision #4
- Appendix IX - per Revision #4
- Appendix X - per Revision #4
- Appendix XI - per Revision #4
- Appendix XII - per Revision #4
- Appendix XIII - per Revision #4
- Informed Consent Form for Protocol Version Date 11/20/06

NSABP-B-39/RTOG-0413

Amendment Review (AR): Amendment #2 (Protocol Version Date 01/08/07)
Documents Posted:

- Summary of Protocol and Consent Changes
- CIRB Application (Protocol Version Date 01/08/07)
- Summary of CIRB Application Revisions
- 02/28/07: Approval Letter
- 01/12/07: Amendment #2 Submission Letter
- Protocol Version Date 01/08/07
- Informed Consent Form for Protocol Version Date 01/08/07

Amendment Review (AR): Amendment #3 (Protocol Version Date 03/13/07)
Documents Posted:

- Summary of Protocol and Consent Changes
- CIRB Application (Protocol Version Date 03/13/07)
- Summary of CIRB Application Revisions
- 04/09/07: Approval Letter
- 03/19/07: Amendment #3 Submission Letter
- Protocol Version Date 03/13/07
- Informed Consent Form for Protocol Version Date 03/13/07

RTOG-0412/SWOG S0332

Amendment Review (AR): Amendment #4 (Protocol Version Date 02/14/07)
Documents Posted:

- Summary of Changes for Amendment #4
- 03/14/07: Approval Letter
- Protocol Version Date 02/14/07



- Protocol Version Date 02/14/07, Tracked Changes

RTOG-0415

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

- Summary of Changes
- CIRB Application (Protocol Version Date 01/24/07)
- Summary of CIRB Application Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 01/24/07
- Protocol Version Date 01/24/07, Tracked Changes
- Informed Consent Form for Protocol Version Date 01/24/07

RTOG-0421

Amendment Review (AR): Amendment #2 (Protocol Version Date 02/14/07)
Documents Posted:

- Summary of Changes
- 03/14/07: Approval Letter
- Protocol Version Date 02/14/07
- Protocol Version Date 02/14/07, Tracked Changes

RTOG-0521

Amendment Review (AR): Amendment #2 (Protocol Version Date 01/24/07)
Documents Posted:

- Summary of Changes
- CIRB Application (Protocol Version Date 01/24/07)
- Summary of CIRB Application Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 01/24/07
- Protocol Version Date 01/24/07, Tracked Changes
- Informed Consent Form for Protocol Version Date 01/24/07

RTOG-0522

Amendment Review (AR): Amendment #3 (Protocol Version Date 02/14/07)
Documents Posted:

- Summary of Changes
- CIRB Application (Protocol Version Date 02/14/07)
- Summary of CIRB Application Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 02/14/07
- Protocol Version Date 02/14/07, Tracked Changes



- Informed Consent Form for Protocol Version Date 02/14/07

SWOG- S0012

Amendment Review (AR): Revision #6 (Protocol Version Date 02/02/07)

Documents Posted:

- 04/03/07: Approval Letter
- Protocol Version Date 02/02/07

SWOG- S0124

Amendment Review (AR): Revision #8 (Protocol Version Date 01/16/07)

Documents Posted:

- CIRB Application (Protocol Version Date 01/16/07)
- Summary of CIRB Application Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 01/16/07

SWOG- S0221

Amendment Review (AR): Revision #1 (Protocol Version Date 01/15/07)

Documents Posted:

- CIRB Application (Protocol Version Date 01/15/07)
- Summary of CIRB Application Revisions
- 03/14/07: Approval Letter
- Protocol Version Date 01/15/07
- Informed Consent Form for Protocol Version Date 01/15/07

SWOG- S0307

Amendment Review (AR): Revision #3 (Protocol Version Date 01/25/07)

Documents Posted:

- CIRB Application (Protocol Version Date 01/25/07)
- Summary of CIRB Application Revisions
- 03/28/07: Approval Letter
- Protocol Version Date 01/25/07
- Informed Consent Form for Protocol Version Date 01/25/07

SWOG- S0427

Amendment Review (AR): Revision #2 (Protocol Version Date 12/13/06)

Documents Posted:

- CIRB Application (Protocol Version Date 08/29/06)
- Summary of CIRB Application Revisions
- 02/02/07: Approval Letter



- 12/13/06: CIRB Response Letter
- 12/11/06: CIRB Approval Pending Modification
- Protocol Version Date 12/13/06
- Protocol Version Date 08/29/06
- Informed Consent Form for Protocol Version Date 12/13/06
- 10/16/06: Primary Reviewer 1 Comments

SWOG- 9007

Amendment Review (AR): Revision #32 (Protocol Version Date 02/27/07)
Documents Posted:

- CIRB Application (Protocol Version Date 02/27/07)
- Summary of CIRB Application Revisions
- 04/10/07: Approval Letter
- Protocol Version Date 02/27/07
- Informed Consent Form for Protocol Version Date 02/27/07

Serious Adverse Events

Study: None
SAE Posted: None

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.