



NCI Central IRB Study Activity Update

August 29, 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

ACOSOG-Z6051

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 06/04/08
- Protocol Version Date 03/17/08
- Protocol Version Date 01/13/08
- Protocol Version Date 10/15/07
- Informed Consent Document for Protocol Version Date 06/04/08
- CIRB Application (Protocol Version Date 06/04/08)
- CIRB Application (Protocol Version Date 03/17/08)
- CIRB Application (Protocol Version Date 10/15/07)
- 04/21/08: Primary Reviewer 1 Comments
- 04/21/08: Primary Reviewer 2 Comments
- 04/21/08: Primary Reviewer 3 Comments
- 11/19/07: Primary Reviewer 1 Comments
- 11/19/07: Primary Reviewer 2 Comments
- 11/19/07: Primary Reviewer 3 Comments
- 08/18/08: ACOSOG Response to CIRB (Protocol Version Date 06/04/08)
- 07/15/08: CIRB Final Approval (Protocol Version Date 06/04/08)
- 05/23/08: CIRB Approval Pending Modification (Protocol Version Date 03/17/08)
- 01/02/08: Withdrawal of CIRB's Initial Review (Protocol Version Date 10/15/07)
- 12/28/07: CIRB Table of Initial Review (Protocol Version Date 10/15/07)
- 04/21/08: Minutes - Initial Review
- 11/19/07: Minutes - Initial Review

ECOG-E1305

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 05/20/08
- Protocol Version Date 03/21/07
- Protocol Version Date 09/27/06
- Informed Consent Document for Protocol Version 05/20/08



- CIRB Application (Protocol Version Date 05/20/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/20/08)
- CIRB Application (Protocol Version Date 03/21/07)
- Summary of CIRB Application Revisions (Protocol Version Date 03/21/07)
- CIRB Application (Protocol Version Date 09/27/06)
- 06/27/08: Primary Reviewer 1 Comments
- 11/20/06: Primary Reviewer 1 Comments
- 11/20/06: Primary Reviewer 2 Comments
- 08/22/08: CIRB Acknowledgement of Posting
- 07/14/08: CIRB Addendum 1 Approval Letter (Protocol Version Date 05/20/08)
- 04/16/07: CIRB Approval Letter (Protocol Version Date 03/21/07)
- 01/22/07: CIRB Approval Pending Modification Letter (Protocol Version Date 09/27/06)
- 06/27/08: Minutes - Addendum 1 Review
- 11/20/06: Minutes - Initial Review

Pediatric CIRB Studies

COG-AOST06P1

Initial Review 2007 Approval
Documents Posted:

- Protocol Version Date 07/01/08
- Protocol Version Date 07/01/08 - Highlighted Changes
- Protocol Version Date 02/29/08
- Protocol Version Date 02/29/08 - Highlighted Changes
- Protocol Version Date 08/16/07
- Informed Consent Document for Protocol Version Date 07/01/08
- CIRB Application (Protocol Version Date 07/01/08)
- CIRB Application (Protocol Version Date 02/29/08)
- CIRB Application (Protocol Version Date 08/16/07)
- 04/10/08: Primary Reviewer 1 Comments
- 10/11/07: Primary Reviewer 1 Comments
- 10/11/07: Primary Reviewer 2 Comments
- 10/11/07: Primary Reviewer 3 Comments
- 10/11/08: Pharmacist Reviewer Comments
- 08/08/08: CIRB Approval Letter (Protocol Version Date 07/01/08)
- 07/01/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/29/08)
- 05/02/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/29/08)
- 04/04/08: Change Memo (Protocol Version Date 02/29/08)
- 10/30/07: CIRB Tabled Letter (Protocol Version Date 08/16/07)



- 04/10/08: Minutes - Group Response to Tabled Initial Review
- 10/11/07: Minutes - Initial Review

Other Activity Posted:

CALGB-40101

Amendment Review (AR) Update #9 Approval August 2008

Documents Posted:

- 07/15/08: Change Memo (Protocol Version Date 06/23/08)
- CIRB Application (Protocol Version Date 06/23/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/23/08)
- Protocol Version Date 06/23/08
- Informed Consent Document for Protocol Version Date 06/23/08 [Per Up 9]
- 08/13/08: CIRB Update 9 Approval Letter (Protocol Version Date 06/23/08)

CALGB-40302

Continuing Review (CR) Approval July 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/02/08)
- 08/14/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/02/08)
- 06/06/08: Continuing Review Reminder Notice
- Protocol Version Date 04/02/08
- Informed Consent Document for Protocol Version Date 04/02/08 [Per Jul 08 CR]
- 07/21/08: Minutes – Continuing Review
- 11/30/07: DSMB Meeting Statements
- November 2007 - Study Summary

CALGB-50303

Amendment Review (AR) Update #6 Approval July 2008

Documents Posted:

- 08/15/08: Change Memo (Protocol Version Date 06/02/08)
- CIRB Application (Protocol Version Date 06/02/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/02/08)
- 07/23/08: CIRB Update 6 Approval Letter (Protocol Version Date 06/02/08)
- Protocol Version Date 06/02/08
- Informed Consent Document for Protocol Version Date 06/02/08 [Per Up 6]
- 07/21/08: Minutes – Update 6



COG-AEPI05N1

Amendment Review (AR) Amendment #1 Approval August 2008

Documents Posted:

- 07/28/08: Change Memo (Protocol Version Date 07/28/08)
- CIRB Application (Protocol Version Date 07/28/08)
- 08/11/08: CIRB Amendment 1 Approval Letter (Protocol Version Date 07/28/08)
- Protocol Version Date 07/28/08
- Protocol Version Date 07/28/08 (Highlighted)
- Informed Consent Document for Protocol Version Date 07/28/08 - CASE SUBJECTS
- Informed Consent Document for Protocol Version Date 07/28/08 - CONTROL SUBJECTS

ECOG-E1A06

Amendment Review (AR) Update #1 Approval April 2008

Documents Posted:

- 02/29/08: Change Memo (Protocol Version Date 02/29/08)
- CIRB Application (Protocol Version Date 02/29/08)
- Summary of CIRB Application Revisions (Protocol Version Date 02/29/08)
- 04/03/08: CIRB Update 1 Approval Letter (Protocol Version Date 02/29/08)
- Protocol Version Date 02/29/08
- Informed Consent Document for Protocol Version Date 02/29/08 [Per Up 1]

ECOG-E1Y03

Amendment Review (AR) Update #2 Approval August 2008

Documents Posted:

- 08/13/08: Change Memo (Protocol Version Date 08/13/08)
- 08/25/08: CIRB Update 2 Approval Letter (Protocol Version Date 08/13/08)
- Protocol Version Date 08/13/08
- Informed Consent Document for Protocol Version Date 08/13/08 [Per Up2]

ECOG-E1899

Continuing Review (CR) July 2008 Approval

Documents Posted:

- 07/31/08: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.



ECOG-E1900

Continuing Review (CR) Approval August 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/14/08)
- 08/20/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/14/08)
- Protocol Version Date 03/12/08
- Informed Consent Document for Protocol Version Date 03/12/08 [Per Aug 08 CR]
- June 2008 Study Summary
- 05/09/08: DMC Recommendations
- Interim Results

ECOG-E3201

Amendment Review (AR) Addendum #5 Approval August 2008
Documents Posted:

- 06/28/08: Change Memo (Protocol Version Date 06/26/08)
- 08/22/08: CIRB Acknowledgement of Posting (Protocol Version Date 06/26/08)
- 08/13/08: CIRB Addendum 5 Approval Letter (Protocol Version Date 06/26/08)
- Protocol Version Date 06/26/08

ECOG-E4402

****Closed to Accrual Effective September 12, 2008****

- 08/15/08: ECOG Closure Notice

ECOG-E4599

Continuing Review (CR) July 2008 Approval
Documents Posted:

- 07/31/08: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

GOG-0213

Amendment Review (AR) Revision #1 Approval June 2008
Documents Posted:

- 05/01/08: Change Memo (Protocol Version Date 05/01/08)
- CIRB Application (Protocol Version Date 05/01/08)



- Summary of CIRB Application Revisions (Protocol Version Date 05/01/08)
- 06/23/08: CIRB Revision 1 Approval Letter (Protocol Version Date 05/01/08)
- Protocol Version Date 05/01/08
- Protocol Version Date 05/01/08 (Highlighted)
- Appendix I FIGO Stage Grouping for Primary Carcinoma of the Ovary
- Informed Consent Document for Protocol Version Date 05/01/08 [Per Rev 1]
- 06/06/08: Minutes - Revision 1 Review
- 08/20/08: CIRB Acknowledgement of Posting Revision 1

GOG-0219

Continuing Review (CR) July 2008 Approval
Documents Posted:

- 07/31/08: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

NCCTG-N0147

Amendment Review (AR) Addendum #9 Approval August 2008
Documents Posted:

- 07/21/08: Change Memo (Protocol Version Date 07/21/08)
- CIRB Application (Protocol Version Date 07/21/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/21/08)
- 08/01/08: CIRB Amendment 1 Approval Letter (Protocol Version Date 07/21/08)
- 07/30/08: DHHS Memo
- 06/06/08: Action Letter
- Protocol Version Date 07/21/08
- Informed Consent Document for Protocol Version Date 07/21/08 [Per Add 9]

NSABP-B-42

Continuing Review (CR) Approval August 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/12/07)
- 08/20/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/12/07)
- 07/28/08: NSABP Cover Letter
- 07/14/08: Continuing Review Reminder Notice
- Protocol Version Date 09/12/07



- Informed Consent Document for Protocol Version Date 09/12/07 (Per Aug 08 CR) Randomized Study
- Informed Consent Document for Protocol Version Date 09/12/07 (Per Aug 08 CR) Optional Registration
- 04/25/08: DMC Minutes
- 10/12/07: DMC Minutes
- 2007 Study Summary

RTOG-0415

Continuing Review (CR) July 2008 Approval
Documents Posted:

- 07/31/08: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

SWOG-9007

Amendment Review (AR) Revision #35 July 2008
Documents Posted:

- 06/23/08: Change Memo (Protocol Version Date 06/23/08)
- CIRB Application (Protocol Version Date 06/23/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/23/08)
- 08/07/08: CIRB Revision 35 Approval Letter (Protocol Version Date 06/23/08)
- Protocol Version Date 06/23/08
- Informed Consent Document for Protocol Version Date 06/23/08 [Per Rev 35]

SWOG-S0200

Continuing Review (CR) Approval July 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/11/07)
- 07/28/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/11/07)
- 06/09/08: Continuing Review Reminder Notice
- Protocol Version Date 06/11/07



SWOG-S0205

Continuing Review (CR) Approval August 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/21/07)
- 08/15/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/21/07)
- 06/09/08: Continuing Review Reminder Notice
- Protocol Version Date 02/21/07
- 04/20/06: DSMC Meeting Minutes

SWOG-S0518

Amendment Review (AR) Revision #1 Approval July 2008

Documents Posted:

- 06/19/08: Change Memo (Protocol Version Date 06/19/08)
 - CIRB Application (Protocol Version Date 06/19/08)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/19/08)
 - 07/23/08: CIRB Revision 1 Approval Letter (Protocol Version Date 06/19/08)
 - Protocol Version Date 06/19/08
 - Informed Consent Document for Protocol Version Date 06/19/08 [Per Rev 1]
 - Informed Consent Document (Notes for Local Institutions & Informed Consent Authors) Protocol Version Date 06/19/08
 - 07/21/08: Minutes – Revision 1
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Corrections to Previous Study Activity Updates

RTOG-0415

Continuing Review (CR) Approval July 2008

Documents Posted:

Informed Consent Document [Tissue] for Protocol Version Date 12/03/07 (***for Currently Enrolled Patients***)

CLARIFICATION:

The phrase "***for Currently Enrolled Patients***" was added to the title of the ***Link*** of the Tissue Consent. There was no change to the actual title of the Tissue Consent Document.

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.