



NCI Central IRB Study Activity Update

November 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.

Adult CIRB Studies

ECOG-E1105

Initial Review 2006 Approval
Documents Posted:

- Protocol Version 09/05/06
- Protocol Version 01/30/07
- Informed Consent for Protocol Version 09/05/06
- Informed Consent for Protocol Version 01/30/07
- CIRB Initial Review Application (Protocol Version 09/05/06)
- Summary of CIRB Application Revisions (Protocol Version 01/30/07)
- CIRB Initial Review Application (Protocol Version 01/30/07)
- 10/20/06: CIRB Member Comments
- 10/19/06: CIRB Member Comments
- 10/15/06: CIRB Member Comments
- 04/13/07: CIRB Initial Review Final Signed Approval March 2007 (Protocol Version 01/30/07)
- 03/14/07: CIRB Initial Review Approval March 2007 (Protocol Version 01/30/07)
- 01/30/07: Group Response Letter
- 12/04/06: CIRB Approval Pending Modifications October 2006 (Protocol Version 09/05/06)
- 09/18/06: CTEP Protocol Approval on Hold (Protocol Version 09/05/06)
- 09/15/06: CTEP-PIO Change Letter
- 09/05/06: Group Letter Listing Changes
- 10/20/06: CIRB Minutes

Other Activity Posted:

ACOSOG-Z1031

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

- CIRB Continuing Review Application (Protocol Version 12/18/06)
- 11/15/07: CIRB Continuing Review Approval October 2007 (Protocol Version 12/18/06)



- 09/17/07: Group Letter
- Protocol Version Date: 12/18/06
- Informed Consent for Protocol Version 12/18/06 [per Oct 07 CR]
- Informed Consent for Protocol Version 12/18/06 Genome Atlas
- Informed Consent for Protocol Version 12/18/06 Spec Bank
- 08/17/07: DMC Minutes
- ADEERS Reports
- 07/17/07: Study Summary

ACOSOG-Z1041

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

- CIRB Continuing Review Application (Protocol Version 05/23/07)
- 11/15/07: CIRB Continuing Review Approval November 2007 (Protocol Version 05/23/07)
- Protocol Version 05/23/07
- Informed Consent for Protocol Version 05/23/07 [per Nov 2007 CR]
- 08/17/07: DMC Minutes
- Report of Studies

CALGB-90401

Amendment Review (AR): Impending Closure to Accrual
Documents Posted:

- 11/20/07: CIRB Acknowledgement of Receipt
- 11/09/07: Notice of Impending Closure to Accrual

COG-AREN0532

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

- CIRB Application (Protocol Version Date 10/16/07)
- CIRB Application (Protocol Version Date 07/06/07)
- 11/06/07: CIRB Approval to Amendment #2 (Protocol Version Date 10/16/07)
- 10/24/07: Group Response Letter
- 09/10/07: CIRB Approval Pending Modification to Amendment #2 (Protocol Version Date 07/06/07)
- Protocol Version Date 10/16/07
- Protocol Version Date 10/16/07 - Highlighted Version
- Protocol Version Date 07/06/07
- Protocol Version Date 07/06/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 10/16/07 -
Chemotherapy Arm



- Informed Consent Form for Protocol Version Date 10/16/07: Observation Arm

ECOG-E1A00

Continuing Review (CR): November 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/30/07)
- 11/15/07: CIRB Continuing Review Approval November 2007 (Protocol Version 05/30/07)
- Protocol Version 05/30/07 [per Nov 07 CR]
- 11/05/03: DMC Report
- Report of Studies (Nov 2004)

ECOG-E1105

Amendment Review (AR): Addendum 2

Documents Posted:

- 11/15/07: CIRB Group Response Approval Nov 2007 (Protocol Version 10/22/07)
- 10/22/07: Group Response Letter
- 10/08/07: CIRB Approval Pending Modification Sept 2007 (Protocol Version 08/24/07)
- Protocol Version 10/22/07 [per Addendum 2 Nov 2007]
- Informed Consent for Protocol Version 10/22/07 (per Addendum 2 Nov 2007)
- 09/17/07: Minutes

ECOG-E1105

Amendment Review (AR): Addendum 1

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Review Application (Protocol Version 05/10/07)
- 07/25/07: CIRB Addendum 1 Review Approval
- 05/21/07: CTEP Notice of Protocol Approval on Hold
- 05/10/07: Group Response to CTEP
- Protocol Version 05/10/07
- Informed Consent for Protocol Version 05/10/07



ECOG-E1105

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

- CIRB Continuing Review Application (Protocol Version 05/10/07)
- 09/10/07: CIRB Continuing Review Approval September 2007 (Protocol Version 05/10/07)
- Protocol Version 05/10/07
- Informed Consent for Protocol Version 05/10/07

GOG-0219

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

- CIRB Continuing Review Application (Protocol Version 11/20/06)
- 11/16/07: CIRB Continuing Review Approval November 2007 (Protocol Version 11/20/07)
- Protocol Version 11/20/06
- Informed Consent Form for Protocol Version Date 11/20/06 [per Nov CR]
- Report of Studies July 2007
- DSMB Minutes July 2007

SWOG-S0221

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

- CIRB Continuing Review Application (Protocol Version 01/15/07)
- 11/15/07: CIRB Continuing Review Approval October 2007 (Protocol Version 01/15/07)
- Protocol Version 01/15/07
- Informed Consent for Protocol Version 01/15/07 [per Oct 2007 CR]
- 09/11/07: SAE Report
- 05/09/07: DSMC Minutes
- 05/03/07: Toxicity Summary



Corrections to Previous Study Activity Updates

GOG-0219

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

- 11/20/07: Erratum-CIRB Continuing Review Approval Nov 2007 (Protocol Version 11/20/06)
- Informed Consent for Protocol Version 11/20/06 [per Nov CR]

Correction:

The GOG 0219 continuing review approval letter dated November 16, 2007 and GOG 0219 consent form for Protocol Version Date 11/20/2006 contain an error in the expiration date. The date should read "August 1, 2008" instead of "November 1, 2008."

COG-AOST0331

Amendment Review (AR): Addendum 2
Documents Posted:

- 6/28/07 Change Letter

Corrections:

06/28/07 Change Letter not previously posted.

Link to 09/21/07: Change Letter renamed 09/21/07: COG Response to Approval Pending Modification

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.