



NCI Central IRB Protocol Activity Update August 1, 2006

The CIRB is distributing this protocol 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@ctisinc.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@ctisinc.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

NCCTG-N0574

Initial Review 2006

Documentation posted:

- Protocol Version 06/14/06
- Protocol Version 05/24/06
- Protocol Version 03/22/06
- Informed Consent for Protocol Version 06/14/06
- CIRB Application Version 03/22/06
- 05/05/06: Primary Reviewer 1 Comments
- 05/05/06: Primary Reviewer 2 Comments
- 06/16/06: CIRB Approval (Protocol Version 06/14/06): Study Chair
- 06/16/06: CIRB Approval (Protocol Version 06/14/06): Local IRB
- 05/24/06: NCCTG Initial Review Response
- 06/14/06: NCCTG Second Review Response
- 05/12/06: Initial Review Approval Pending Modification (Protocol Version 03/22/06)
- 06/13/06: Group Response Approval Pending Modification (Protocol Version 05/24/06)
- 03/22/06, NCCTG Response to CTEP Review
- 07/28/06, Forms Packet
- 05/05/06: Initial Review Meeting Minutes

Other Activity Posted:

ACOSOG-Z4032

Continuing Review September 2006

Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

CALGB-40101

Continuing Review September 2006

Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

CALGB-80303

Amendment Review: Update #5 (Protocol Version 03/01/06)

Documentation posted:

- 06/02/06, Minutes: Amendment Review June 2006



Memo: Treatment Unblinding Response Form (C-1560)
Documentation posted:

- 07/26/06, CIRB Acknowledgement of Treatment Unblinding Response Form (C-1560)
- Treatment Unblinding Response Form (C-1560)

CALGB-SWOG C80405

Amendment Review: Update #2 (Protocol Version 05/22/06)
Documentation posted:

- 06/19/06: Primary Reviewer Comments
- 06/19/06, Minutes: Amendment #2 Review June 2006

COG-AALL03B1

Continuing Review September 2006
Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

COG-ACCL04C2

Continuing Review October 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for October 2006

COG-ACNS0221

Continuing Review October 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for October 2006

COG-AHOD03P1

Continuing Review October 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for October 2006

COG-AOST0331

Initial Review 2005
Documentation posted:

- EURAMOS 1 (Protocol Version 1.0, 30 September, 2004)

COG-ARAR0331



Continuing Review October 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for October 2006

COG-ARET0331

Continuing Review October 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for October 2006

COG-ARST03P1

Continuing Review September 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for September 2006

COG-ARST0431

Amendment Review: Amendment #2 (Protocol Version 06/20/06)
Documentation posted:

- 06/20/06, Change Memo
- CIRB Application Version 06/20/06
- 07/11/06: CIRB Approval (Protocol Version 06/20/06): Study Chair
- 07/11/06: CIRB Approval (Protocol Version 06/20/06): Local IRB
- Protocol Version 06/20/06
- Protocol Version 06/20/06, Highlighted Changes
- Informed Consent for Protocol Version 06/20/06

Continuing Review September 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for September 2006

COG-D9902

Continuing Review September 2006
Documentation posted:

- 07/21/06, Continuing Review Notice for September 2006

ECOG E1302

Continuing Review June 2006
Documentation posted:

- 06/19/06, Minutes: Continuing Review June 2006



ECOG-E1900

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

GOG-0198

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

GOG-0204

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

GOG-0209

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

GOG-0212

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

GOG-0218

Amendment Review: Revision #2 (Protocol Version 05/12/06)
Documentation posted:

- 05/12/06, Change Memo
- CIRB Application Version 05/12/06
- 05/12/06: Summary of CIRB Application Revisions
- 06/21/06, Approval to Revision #2 (Protocol Version 05/12/06): Local IRB
- 06/21/06, Approval to Revision #2 (Protocol Version 05/12/06): Study Chair
- Protocol Version 05/12/06
- Informed Consent for Protocol Version 05/12/06
- 06/19/06: Primary Reviewer 1 Comments
- 06/19/06, Minutes: Amendment #2 Review

NCIC CTG-MA.27

Continuing Review July 2006



Documentation posted:

- CIRB Continuing Review Application Version 01/30/06
- 07/18/06, CIRB Approval to Continuing Review July 2006 (Protocol Version 01/30/06)
- Protocol Version 01/30/06
- Informed Consent for Protocol Version 01/30/06
- Continuing Review 2006: DSMC Minutes
- Continuing Review 2005: ROS and Toxicity Report

NSABP-B-33

Continuing Review June 2006

Documentation posted:

- 06/19/06, Minutes: Continuing Review June 2006

NSABP-C-08

Amendment Review: Amendment #5 (Protocol Version 4/21/06)

Documentation posted:

- 06/02/06, Minutes: Amendment Review June 2006

NSABP-R-04

Continuing Review June 2006

Documentation posted:

- 06/02/06, Minutes: Continuing Review June 2006

RTOG-0214

Continuing Review July 2006

Documentation posted:

- Continuing Review July 2006: Group Continuing Review Application
- 07/18/06, CIRB Approval to Continuing Review July 2006 (Protocol Version 12/08/05)
- Protocol Version 12/08/05 (per Amendment #4)
- Informed Consent for Protocol Version 12/08/05 (per July 2006 CR)
- 06/06, DMC Special Accrual Report
- 01/06, Meeting Summary

RTOG-0525

Continuing Review September 2006

Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006



RTOG-BR-0118

Continuing Review September 2006

Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

SWOG-9007

Continuing Review September 2006

Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

Amendment Review: Revision #30 (Protocol Version 05/22/06)

Documentation posted:

- CIRB Application Version 05/22/06
- 06/09/06, CIRB Approval to Revision #30 (Protocol Version 05/22/06):
Local IRB
- 06/09/06, CIRB Approval to Revision #30 (Protocol Version 05/22/06):
Study Chair
- Protocol Version 05/22/06
- Informed Consent for Protocol Version 05/22/06

SWOG-S0106

Continuing Review September 2006

Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

SWOG-S0124

Continuing Review July 2006

Documentation posted:

- CIRB Continuing Review Application Version 09/01/05
- 07/18/06, CIRB Approval to Continuing Review July 2006 (Protocol Version 09/01/05)
- Protocol Version 09/01/05
- Informed Consent for Protocol Version 09/01/05 (per July 2006 CR)
- Published Paper
- DSMB Report dated 05/19/06
- Toxicity Summary
- SAE Listing

SWOG-S0309



Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

SWOG-S0427

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

SWOG-S9910

Continuing Review September 2006
Documentation posted:

- 07/24/06, Continuing Review Notice for September 2006

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@ctisinc.com.