



NCI Central IRB Study Activity Update October 16, 2006

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@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

SWOG-S0500

Initial Review 2006
Documents Posted:

- Protocol Version 07/12/06
- Protocol Version 05/10/06
- Informed Consent for Protocol Version 07/12/06
- CIRB Application Version 07/12/06
- CIRB Application Version 05/10/06
- Summary of CIRB Application Revisions Version 07/12/06
- 06/19/06: Primary Reviewer 1 Comments
- 06/19/06: Primary Reviewer 2 Comments
- 08/01/06: CIRB Approval (Protocol Version 07/12/06)
- 07/13/06: SWOG Response to Approval Pending Modification
- 06/29/06: Approval Pending Modification (Protocol Version 05/10/06)
- 06/19/06: Initial Review Meeting Minutes

Other Activity Posted:

CALGB-40101

Continuing Review (CR) September 2006
Documents Posted:

- CIRB Continuing Review Application Version 04/11/06
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 04/11/06)
- Protocol Version 04/11/06
- Informed Consent for Protocol Version 04/11/06 [Per Sept. 06 CR]
- Study Summary Dated June 2006
- 06/16/06, DSMC Report

CALGB-49907

Continuing Review (CR) August 2006
Documents Posted:

- CIRB Continuing Review Application Version 02/24/06
- 08/21/06, CIRB Approval to Continuing Review August 2006 (Protocol Version 02/24/06)
- 06/21/06, Continuing Review Notice for August 2006



- Protocol Version 02/24/06
- Informed Consent for Protocol Version 02/24/06 [Per Aug. 06 CR]
- Y-ME Informed Consent for Protocol Version 02/24/06 [Per Aug. 06 CR]
- 06/16/06, DSMB Recommendations
- June 2006 Study Summary

CALGB-90401

Amendment Review: Update #2 (Protocol Version 07/06/06)

Documents Posted:

- 07/06/06, Change Memo
- CIRB Application Version 07/06/06
- Summary of CIRB Application Revisions
- 08/18/06: CIRB Acknowledgement of Activation
- 07/16/06: CIRB Approval to Update #2 (Protocol Version 07/06/06)
- 07/07/06: CALGB Response to Approval Pending Modification
- 06/23/06: Approval Pending Modification (Protocol Version 04/26/06)
- Protocol Version 07/06/06
- Informed Consent for Protocol Version 07/06/06
- 06/19/06: Primary Reviewer 1 Comments
- 06/19/06, Minutes: Update #2 Review

COG-AALL0331

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 10/06/06: CIRB Acknowledgement of Expanding institutional participation in AALL0331-HRQOL
- 10/06/06: Memo of Expanding institutional participation in AALL0331-HRQOL

COG-AALL03B1

Amendment Review: Amendment #3A (Protocol Version 08/01/06)

Documents Posted:

- 08/01/06, Change Memo
- CIRB Application Version 08/01/06
- 08/04/06: CIRB Approval to Amendment #3A (Protocol Version 08/01/06)
- 08/14/06: CIRB Acknowledgement of Activation
- Protocol Version 08/01/06
- Protocol Version 08/01/06, Highlighted Changes
- Informed Consent for Protocol Version 08/01/06



COG-AALL03N1

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 08/28/06: CIRB Acknowledgement of Revised "Eligibility Screening Tool" for AALL03N1, Understanding the Ethnic.....
- 08/25/06: Memo of Revised "Eligibility Screening Tool" for AALL03N1, Understanding the Ethnic.....
- 08/28/06: CIRB Acknowledgement of AALL03N1 Regarding Version 02 COG Sample Consent.....
- 08/25/06: Memo of AALL03N1 Regarding Version 02 COG Sample Consent.....
- 08/28/06: CIRB Acknowledgement of Closure of Enrollment to Caucasian Patients on AALL03N1.....
- 08/25/06: Memo of Closure of Enrollment to Caucasian Patients on AALL03N1.....

COG-ACNS0221

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application Version 11/15/05
- 10/12/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 11/15/05)
- Protocol Version 11/15/05
- Informed Consent for Protocol Version 11/15/05 [Per Oct. 06 CR]
- Study Progress Report Dated 09/05/06

COG-AHOD03P1

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application Version 12/08/05
- 10/12/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 12/08/05)
- Protocol Version 12/08/05
- Informed Consent for Protocol Version 12/08/05 [Per Oct. 06 CR]

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:



- 10/02/06: CIRB Acknowledgement of Revised AHOD03P1 Data Submission Schedule
- 09/08/06: Memo of Revised AHOD03P1 Data Submission Schedule

COG-ANHL04B1

Amendment Review: Amendment #2 (Protocol Version 09/19/06)

Documents Posted:

- 06/30/06, Change Memo
- CIRB Application Version 09/19/06
- CIRB Application Version 06/30/06
- 09/26/06: CIRB Approval to Amendment #2 (Protocol Version 09/19/06)
- Protocol Version 09/19/06
- Protocol Version 09/19/06, Highlighted Changes
- Protocol Version 06/30/06
- Protocol Version 06/30/06, Highlighted Changes
- Informed Consent for Protocol Version 09/19/06
- 08/10/06, Minutes: Amendment #2 Review

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 10/06/06: CIRB Acknowledgement of Rare and Cutaneous Non-Hodgkin Lymphoma Registry - Study.....
- 10/06/06: Memo of Rare and Cutaneous Non-Hodgkin Lymphoma Registry - Study.....
- 10/02/06: CIRB Acknowledgement of Activation of Amendment #2
- 10/02/06: Memo of Activation of Amendment #2

COG-ARAR0331

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application Version 05/25/05
- 10/12/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 05/25/05)
- Protocol Version 05/25/05
- Informed Consent for Protocol Version 05/25/06 [Per Oct. 06 CR]
- Study Progress Report Dated 05/31/06

COG-ARET0331

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page



Documents Posted:

- 10/02/06: CIRB Acknowledgement of Revised Targeted Toxicity Form
- 09/29/06: Memo of Revised Targeted Toxicity Form

COG-ARET0332

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 10/06/06: CIRB Acknowledgement of Revised Eligibility and OnStudy Forms
- 10/06/06: Memo of Revised Eligibility and OnStudy Forms
- 10/02/06: CIRB Acknowledgement of Activation of Amendment #1A
- 10/02/06: Memo of Activation of Amendment #1A

Amendment Review: Amendment #1A (Protocol Version 09/05/06)

Documents Posted:

- 09/05/06, Change Memo
- CIRB Application Version 09/05/06
- 09/21/06: CIRB Approval to Amendment #1A (Protocol Version 09/05/06)
- Protocol Version 09/05/06
- Informed Consent for Protocol Version 09/05/06: Chemotherapy Arm
- Informed Consent for Protocol Version 09/05/06: Observation Arm

Amendment Review: Amendment #1 (Protocol Version 08/02/06)

Documents Posted:

- 08/02/06, Change Memo
- CIRB Application Version 08/02/06
- 08/22/06: CIRB Approval to Amendment #1 (Protocol Version 08/02/06)
- Protocol Version 08/02/06
- Protocol Version 08/02/06, Highlighted Changes
- Informed Consent for Protocol Version 08/02/06: Chemotherapy Arm
- Informed Consent for Protocol Version 08/02/06: Observation Arm

COG-ARST03P1

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 01/12/06



- 09/29/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 01/12/06)
- Protocol Version 01/12/06
- Informed Consent for Protocol Version 01/12/06 [Per Sept. 06 CR]: Observation
- Informed Consent for Protocol Version 01/12/06 [Per Sept. 06 CR]: Drug Therapy
- 03/29/06, DSMC Report
- Study Progress Report Dated 09/05/06

COG-D9902

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 01/30/06
- 09/29/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 01/30/06)
- Protocol Version 01/30/06
- Informed Consent for Protocol Version 01/30/06 [Per Sept. 06 CR]

ECOG-E1900

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 12/30/04
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 12/30/04)
- Protocol Version 12/30/04 (Per Addendum #7)
- Informed Consent for Protocol Version 12/30/04 [Per Sept. 06 CR]
- 04/28/06, DMC Report
- Study Progress Report Dated June 2006

ECOG-E2603

Amendment Review: Addendum #7 (Protocol Version 08/28/06)

Documents Posted:

- 08/28/06, Change Memo
- CIRB Application Version 08/28/06
- Summary of CIRB Application Revisions Version 08/28/06
- 08/28/06: CIRB Approval to Addendum #7 (Protocol Version 08/28/06)
- 08/28/06: ECOG Response to Approval Pending Modification
- Protocol Version 08/28/06
- Informed Consent for Protocol Version 08/28/06



GOG-0198

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 11/09/05
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 11/09/05)
- Protocol Version 11/09/05
- Informed Consent for Protocol Version 11/09/05 [Per Sept. 06 CR]
- Statistical Report Dated July 2006

GOG-0204

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 07/26/06
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 07/26/06)
- Protocol Version 10/14/05
- Informed Consent for Protocol Version 10/14/05 [Per Sept. 06 CR]
- Statistical Report Dated July 2006

GOG-0209

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 02/13/06
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 02/13/06)
- Protocol Version 02/13/06
- Informed Consent for Protocol Version 02/13/06 [Per Sept. 06 CR]
- 01/21/06, DSMB Minutes
- Statistical Report Dated July 2006

NCCTG-N0434 (M.A. 27D)

Amendment Review: Addendum #2 (Protocol Version 06/28/06)

Documents Posted:

- CIRB Application Version 06/28/06
- Summary of CIRB Application Revisions Version 06/28/06
- 08/21/06: CIRB Approval to Addendum #2 (Protocol Version 06/28/06)
- Protocol Version 06/28/06
- Informed Consent for Protocol Version 06/28/06
- 08/04/06: Primary Reviewer 1 Comments
- 08/04/06, Minutes: Addendum #2 Review



SWOG-9007

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 05/22/06
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 05/22/06)
- Protocol Version 05/22/06
- Informed Consent for Protocol Version 05/22/06 [Per Sept. 06 CR]
- Study Progress Report Dated June 2006

SWOG-S0106

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 05/02/05
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 05/02/05)
- Protocol Version 05/02/05 (Includes Revision #3)
- Informed Consent for Protocol Version 05/02/05 [Per Sept. 06 CR]
- 05/19/06, DSMC Minutes
- Study Progress Report Dated June 2006

SWOG-S0309

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 02/27/06
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 02/27/06)
- Protocol Version 04/28/05 (Includes Revision #5)
- Study Progress Report Dated June 2006

SWOG-S9910

Continuing Review (CR) September 2006

Documents Posted:

- CIRB Continuing Review Application Version 02/09/06
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 02/09/06)
- Protocol Version 02/09/06
- Informed Consent for Protocol Version 02/09/06 [Per Sept. 06 CR]
- Study Progress Report Dated June 2006



SWOG-S9925

Continuing Review (CR) September 2006
Documents Posted:

- CIRB Continuing Review Application Version 07/25/06
- 08/08/06, Continuing Review Notice for September 2006
- 09/27/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 07/25/06)
- Protocol Version 07/25/06
- 06/30/06, Addendum 1

Serious Adverse Events

Study: NCIC CTG MA.27
SAE Posted: MA27-15

Study: RTOG 0320
SAEs Posted: 2006SP000744, 2006-08-0388 (1), 2006-07-1249 (1), 2006SP000744 (1)

Study: RTOG 0522
SAEs Posted: DDL 188 (4) / 05-02-06785 (4), DDL 223 (2) / 06-02-09194 (2), DDL 230 / 06-02-10236, DDL 231 / 06-02-07687, DDL 150 (1) / 05-02-05249 (1)

Study: RTOG 0525
SAEs Posted: 2006SP000744, 2006-08-0388 (1), 2006-07-1249 (1), 2006SP000744 (1)

Study: SWOG S0205
SAEs Posted: DDL 188 (4) / 05-02-06785 (4), DDL 223 (2) / 06-02-09194 (2)

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.