



NCI Central IRB Study Activity Update November 1, 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

CALGB 40302

Initial Review 2005

Documents Posted:

- Protocol Version 12/01/05
- Protocol Version 10/27/05
- Protocol Version 09/19/05
- Protocol Version 04/19/05
- Informed Consent for Protocol Version 12/01/05
- CIRB Application Version 09/19/05
- 11/21/05: Primary Reviewer 1 Comments
- 11/21/05: Primary Reviewer 2 Comments
- 10/17/05: Primary Reviewer 1 Comments
- 10/17/05: Primary Reviewer 2 Comments
- 07/18/05: Primary Reviewer 1 Comments
- 07/18/05: Primary Reviewer 2 Comments
- 12/06/05: CIRB Approval (Protocol Version 12/01/05): Local IRB
- 12/06/05: CIRB Approval (Protocol Version 12/01/05): Study Chair
- 11/29/05: Approval Pending Modification (Protocol Version 10/27/05)
- 10/31/05: CALGB Response to Tabled Action (Protocol Version 10/27/05)
- 10/27/05: CIRB Tabled Letter (Protocol Version 09/19/05)
- 09/28/05: CALGB Response to Approval Pending Modification
- 08/11/05: Approval Pending Modification (Protocol Version 04/19/05)
- 11/21/05: Initial Review Meeting Minutes
- 07/18/05: Initial Review Meeting Minutes

Pediatric CIRB Studies

COG-AHOD04B1

Initial Review 2006

Documents Posted:

- Protocol Version 06/26/06
- Protocol Version 06/26/06, Highlighted Changes
- Protocol Version 03/10/06
- Informed Consent for Protocol Version 06/26/06
- CIRB Application Version 06/26/06
- 06/29/06: CIRB Approval (Protocol Version 06/26/06): Local IRB
- 06/29/06: CIRB Approval (Protocol Version 06/26/06): Study Chair
- 06/19/06: Approval Pending Modification (Protocol Version 03/10/06)



- 06/26/06: COG Response to Approval Pending Modification
- 06/08/06: Initial Review Meeting Minutes

COG-AREN0532

Initial Review 2006

Documents Posted:

- Protocol Version 05/08/06
- Protocol Version 05/08/06, Highlighted Changes
- Protocol Version 03/09/06
- Informed Consent for Protocol Version 05/08/06: Chemotherapy Arm
- Informed Consent for Protocol Version 05/08/06: Observation Arm
- CIRB Application Version 05/08/06
- CIRB Application Version 03/09/06
- 04/13/06: Pharmacist Comments
- 04/13/06: Primary Reviewer 1 Comments
- 04/13/06: Primary Reviewer 2 Comments
- 04/13/06: Primary Reviewer 3 Comments
- 08/05/06: COG Response to Approval Pending Modification
- 05/16/06: CIRB Approval (Protocol Version 05/08/06): Study Chair
- 05/16/06: CIRB Approval (Protocol Version 05/08/06): Local IRB
- 04/21/06: Approval Pending Modification (Protocol Version 03/09/06)
- 04/13/06: Initial Review Meeting Minutes

Other Activity Posted:

CALGB 40302

Amendment Review: Special Protocol Assessment (Protocol Version 05/09/06)

Documents Posted:

- 05/09/06: Change Memo
- CIRB Application Version 05/09/06
- Summary of CIRB Application Revisions Version 05/09/06
- 06/09/06: CIRB Approval to Special Protocol Assessment (Protocol Version 05/09/06)
- Protocol Version 05/09/06
- Informed Consent for Protocol Version 05/09/06
- 06/02/06: Primary Reviewer 1 Comments
- 06/02/06: Minutes: Special Protocol Assessment Review

CALGB-80101

Amendment Review: Update #4 (Protocol Version 07/07/06)

Documents Posted:



- 10/15/06: Change Memo
- CIRB Application Version 07/07/06
- Summary of CIRB Application Revisions Version 07/07/06
- 08/28/06: CIRB Approval to Update #4 (Protocol Version 07/07/06)
- Protocol Version 07/07/06
- Informed Consent for Protocol Version 07/07/06

CALGB-80203

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/23/05)
- 08/08/06, Continuing Review Notice for October 2006
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 06/23/05)
- Protocol Version 06/23/05 (Includes Update #4)
- Informed Consent for Protocol Version 06/23/05 [Per Oct. 06 CR]
- Study Abstract
- 10/17/06, Toxicity Summary

CALGB-80303

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/30/06)
- 08/08/06, Continuing Review Notice for October 2006
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 03/01/06)
- Protocol Version 03/01/06
- Informed Consent for Protocol Version 03/01/06 [Per Oct. 06 CR]
- 10/17/06, Toxicity Summary

CALGB-90202

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 11/07/05)
- 08/08/06, Continuing Review Notice for October 2006
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 11/07/05)
- Protocol Version 11/07/05
- Informed Consent for Protocol Version 11/07/05 [Per Oct. 06 CR]
- Study Summary Dated June 2005



COG-AALL0331

Amendment Review: Amendment #1A (Protocol Version 09/25/06)

Documents Posted:

- CIRB Application Version 09/25/06
- 10/06/06: CIRB Approval to Amendment #1A (Protocol Version 09/25/06)
- 09/25/06: COG Response to Approval Pending Modification (Protocol Version 09/25/06)
- Protocol Version 09/25/06
- Protocol Version 09/25/06, Highlighted Changes
- Informed Consent for Protocol Version 09/25/06: Standard Risk - Average
- Informed Consent for Protocol Version 09/25/06: Standard Risk - High
- Informed Consent for Protocol Version 09/25/06: Induction Therapy
- Informed Consent for Protocol Version 09/25/06: Standard Risk - Low
- 09/14/06, Minutes: Amendment #1A Review

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

Documents Posted:

- 10/23/06: CIRB Acknowledgement of Activation of Amendment #1A/ BRIEFING FOR NEW SITES/ Amendment #1 Revisions.....
- 10/23/06: Memo of Activation of Amendment #1A
- 10/20/06: Memo of BRIEFING FOR NEW SITES: AALL0331-HRQOL data collection
- 10/20/06: Memo of Amendment #1 Revisions to Eligibility CRF and eRDE Screen
- 10/16/06: CIRB Acknowledgement of POST-INDUCTION TREATMENT RANDOMIZATION/ASSIGNMENT.....
- 10/13/06: Memo of POST-INDUCTION TREATMENT RANDOMIZATION/ASSIGNMENT.....

COG-AALL03B1

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

Documents Posted:

- 10/30/06: CIRB Acknowledgement of Classification of Acute Lymphoblastic Leukemia/ Updates to AALL03B1.....
- 10/27/06: Memo of Classification of Acute Lymphoblastic Leukemia
- 10/27/06: Memo of Updates to AALL03B1, Classification of Acute Lymphoblastic Leukemia



COG-AAML0121

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

Documents Posted:

- 10/23/06: CIRB Acknowledgement of A Phase II Study of Amifostine in Children with Myelodysplastic Syndrome
- 10/20/06: Memo of A Phase II Study of Amifostine in Children with Myelodysplastic Syndrome

COG-ACCL04C2

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/08/05)
- 10/26/06: CIRB Approval to Continuing Review October 2006 (Protocol Version 08/08/05)
- 10/23/06: Approval Pending Modification (Protocol Version 08/08/05)
- Protocol Version 08/08/05
- Informed Consent for Protocol Version 08/08/05 [Per Oct. 06 CR]

COG-ACNS0224

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

Documents Posted:

- 10/30/06: CIRB Acknowledgement of A Phase I/II Study of Topotecan with G-CSF and Radiation Therapy In Children.....
- 10/27/06: Memo of A Phase I/II Study of Topotecan with G-CSF and Radiation Therapy In Children.....

COG-AHOD04B1

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

Documents Posted:

- 10/23/06: CIRB Acknowledgment of Activation of AHOD04B1
- 10/20/06: Memo of Activation of AHOD04B1

Amendment Review: Activation Amendment (Protocol Version 09/21/06)

Documents Posted:

- CIRB Application Version 09/21/06
- 09/27/06: CIRB Approval (Protocol Version 09/21/06)
- Protocol Version 09/21/06



- Protocol Version 09/21/06, Highlighted Changes
- Informed Consent for Protocol Version 09/21/06

COG-ANBL00B1

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

Documents Posted:

- 10/23/06: CIRB Acknowledgment of Amendment #7 for study ANBL00B1, Neuroblastoma Biology
- 10/20/06: Memo of Amendment #7 for study ANBL00B1, Neuroblastoma Biology

Amendment Review: Amendment #6 (Protocol Version 08/18/06)

Documents Posted:

- 08/18/06: Change Memo
- CIRB Application Version 08/18/06
- 10/16/06: CIRB Acknowledgement of Activation
- 10/16/06: Study Activation
- 10/06/06: CIRB Approval to Amendment #6 (Protocol Version 08/18/06)
- Protocol Version 08/18/06
- Protocol Version 08/18/06, Highlighted Changes
- Informed Consent for Protocol Version 08/18/06

COG-ANBL00P3

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

Documents Posted:

- 10/23/06: CIRB Acknowledgement of ANBL00P3 No Objection Letter for the Quality Amendment
- 10/20/06: Memo of ANBL00P3 No Objection Letter for the Quality Amendment

COG-ANBL0421

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

Documents Posted:

- 10/30/06: CIRB Acknowledgement of A Phase II Study of Irinotecan + Temozolomide.....
- 10/27/06: Memo of A Phase II Study of Irinotecan + Temozolomide.....



COG-AREN0321

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/08/05)
- 10/27/06: CIRB Approval to Continuing Review October 2006 (Protocol Version 08/08/06)
- 09/20/06: Continuing Review Notice for October 2006
- Protocol Version 08/08/06
- Protocol Version 08/08/06, Highlighted Changes
- Informed Consent for Protocol Version 08/08/06 [Per Oct. 06 CR]: Regimen DD-4A
- Informed Consent for Protocol Version 08/08/06 [Per Oct. 06 CR]: Observation
- Informed Consent for Protocol Version 08/08/06 [Per Oct. 06 CR]: Regimen I
- Informed Consent for Protocol Version 08/08/06 [Per Oct. 06 CR]: Regimen UH1
- Informed Consent for Protocol Version 08/08/06 [Per Oct. 06 CR]: Window Therapy

COG-AREN03B2

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

Documents Posted:

- 10/16/06: CIRB Acknowledgment of eRDES Document Imaging
- 10/13/06: Memo of eRDES Document Imaging

COG-AREN0532

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

Documents Posted:

- 10/30/06: CIRB Acknowledgement of Activation of AREN0532
- 10/30/06: Memo of Activation of AREN0532

Amendment Review: Amendment #1 (Protocol Version 07/28/06)

Documents Posted:

- CIRB Application Version 07/28/06
- 09/21/06: CIRB Approval to Amendment #1 (Protocol Version 07/28/06)
- Protocol Version 07/28/06
- Protocol Version 07/28/06, Highlighted Changes



- Informed Consent for Protocol Version 07/28/06: Chemotherapy Arm
- Informed Consent for Protocol Version 07/28/06: Observation Arm
- 09/14/06, Minutes: Amendment #1 Review

COG-ARET0332

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/05/06)
- CIRB Continuing Review Application (Protocol Version 05/06/05)
- 10/26/06: CIRB Approval to Continuing Review October 2006 (Protocol Version 09/05/06)
- 10/08/06, COG Response
- 10/06/06: CIRB Tabled Letter (Protocol Version 05/06/05)
- 06/27/06, Continuing Review Notice for October 2006
- Protocol Version 09/05/06
- Informed Consent for Protocol Version 09/05/06 [Per Oct. 06 CR]: Chemotherapy Arm
- Informed Consent for Protocol Version 09/05/06 [Per Oct. 06 CR]: Observation Arm
- 09/28/06, Minutes: Continuing Review October 2006
- 03/29/06, DSMC Report
- Study Progress Report Dated 09/05/06

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

Documents Posted:

- 10/23/06: CIRB Acknowledgement of Revised Case Report Forms/ A Study of Unilateral Retinoblastoma.....
- 10/20/06: Memo of Revised Case Report Forms
- 10/20/06: Memo of A Study of Unilateral Retinoblastoma With and Without Features.....

ECOG-E2805

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/14/06)
- 08/08/06: Continuing Review Notice for October 2006
- 10/24/06: CIRB Approval to Continuing Review October 2006 (Protocol Version 06/14/06)
- Protocol Version 6/14/06
- Informed Consent for Protocol Version 06/14/06 [Per Oct. 06 CR]



ECOG-E3999

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/01/05)
- 08/08/06, Continuing Review Notice for October 2006
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 06/01/05)
- Protocol Version 06/01/05
- Informed Consent for Protocol Version 06/01/05 [Per Oct. 06 CR]
- 04/18/06, DMC Report
- Study Progress Report Dated June 2006

ECOG-E5204

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/24/06)
- 08/08/06, Continuing Review Notice for October 2006
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 12/22/05)
- Protocol Version 12/22/05
- Informed Consent for Protocol Version 12/22/05 [Per Oct. 06 CR]
- Study Progress Report Dated June 2006
- 04/18/06, DMC Report

GOG-0198

Amendment Review: Revision #6 (Protocol Version 08/15/06)

Documents Posted:

- 08/15/06: Change Memo
- CIRB Application Version 08/15/06
- Summary of CIRB Application Revisions Version 08/15/06
- 09/06/06: CIRB Approval to Revision #6 (Protocol Version 08/15/06)
- Protocol Version 08/15/06
- Appendices I-V (Protocol Version 08/15/06)
- Informed Consent for Protocol Version 08/15/06

GOG-0204

Amendment Review: Revision #6 (Protocol Version 09/06/06)

Documents Posted:

- 09/06/06: Change Memo
- CIRB Application Version 09/06/06
- Summary of CIRB Application Revisions Version 09/06/06



- 10/05/06: CIRB Approval to Revision #6 (Protocol Version 09/06/06)
- Protocol Version 09/06/06
- Appendices I-II (Protocol Version 09/06/06)
- Informed Consent for Protocol Version 09/06/06

Amendment Review: Revision #5 (Protocol Version 07/26/06)
Documents Posted:

- 07/26/06: Change Memo
- CIRB Application Version 07/26/06
- Summary of CIRB Application Revisions Version 07/26/06
- 08/25/06: CIRB Approval to Revision #5 (Protocol Version 07/26/06)
- Protocol Version 07/26/06
- Appendices I-II (Protocol Version 07/26/06)
- Informed Consent for Protocol Version 07/26/06

GOG-0212

Amendment Review: Revision #3 (Protocol Version 09/14/06)
Documents Posted:

- 05/26/06: Change Memo
- CIRB Application Version 05/26/06
- Summary of CIRB Application Revisions Version 05/26/06
- 10/13/06: CIRB Approval to Revision #3 (Protocol Version 09/14/06)
- 09/14/06: GOG Response to Approval Pending Modification (Protocol Version 05/26/06)
- 08/08/06: CIRB Tabled Letter (Protocol Version 05/26/06)
- Protocol Version 09/14/06
- Informed Consent for Protocol Version 09/14/06

Continuing Review (CR) October 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/12/06)
- 10/12/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 01/12/06)
- Protocol Version 01/12/06
- Informed Consent for Protocol Version 01/12/06 [Per Oct. 06 CR]

GOG-0219

Amendment Review: Revision #3 (Protocol Version 06/28/06)
Documents Posted:



- 06/28/06: Change Memo
- CIRB Application Version 06/28/06
- Summary of CIRB Application Revisions Version 06/28/06
- 09/12/06: CIRB Approval to Revision #3 (Protocol Version 06/28/06)
- 08/23/06: GOG Response to Approval Pending Modification (Protocol Version 06/28/06)
- 08/21/06: Approval Pending Modification (Protocol Version 06/28/06)
- Protocol Version 06/28/06
- Appendices I-XIII (Protocol Version 06/28/06)
- Informed Consent for Protocol Version 06/28/06

NCIC-CTG-MA.27B

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/31/06)
- 08/08/06, Continuing Review Notice for October 2006
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 03/31/06)
- Protocol Version 03/31/06
- Informed Consent for Protocol Version 03/31/06 [Per Oct. 06 CR]

RTOG-0525

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/12/06)
- 10/13/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 06/12/06)
- Protocol Version 06/12/06
- Informed Consent for Protocol Version 06/12/06 [Per Oct. 06 CR]
- Study Progress Report Dated June 2006
- 06/16/06, DMC Minutes

RTOG-BR-0118

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 10/31/03)
- 09/25/06, CIRB Approval to Continuing Review October 2006 (Protocol Version 10/31/03)
- Protocol Version 10/31/03
- Study Progress Report Dated June 2006
- 06/16/06, DMC Minutes



Serious Adverse Events

**Study: CALGB 10201
SAE Posted: 1744313**

**Study: CALGB 100104 – ECOG 100104
SAE Posted: 1384463**

**Study: ECOG E2902
SAE Posted: 1590721**

**Study: ECOG E4A03
SAE Posted: 1384463**

**Study: GOG 0219
SAE Posted: 1479316**

**Study: NSABP B-34
SAEs Posted: Safety Update #31, Safety Update #30 (Follow-up #1), Safety Update #29 (Follow-up #1), Safety Update #32, Safety Update #31 (Follow-up #1), Safety Update #33**

**Study: NSABP B-38
SAEs Posted: Safety Update #89, Safety Update #90, Safety Update #91, Safety Update #74 (Follow-up #1), Safety Update #92, Safety Update #93, Safety Update #94, Safety Update #80 (Follow-up #1), Safety Update #79 (Follow-up #1), Safety Update #89 (Follow-up #1), Safety Update #95, Safety Update #92 (Follow-up #1), Safety Update #96, Safety Update #97, Safety Update #90 (Follow-up #1)**

**Study: RTOG 0320
SAE Posted: 2006-08-0388**

**Study: RTOG 0522
SAEs Posted: DDL 229 / 06-02-07854**

**Study: RTOG 0525
SAE Posted: 2006-08-0388**

**Study: SWOG S0124
SAE Posted: 2006097842**

**Study: SWOG S0200
SAE Posted: 20060704939 (0)**

Study: SWOG S0205



**SAEs Posted: DDL 116 (2) / 04-02-04123 (2), DDL 224 (1) / 06-02-09124 (1),
DDL 188 (3) / 05-02-06785 (3), DDL 229 / 06-02-07854**

**Study: SWOG S0232
SAE Posted: 1384463**

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.