



NCI Central IRB Study Activity Update January 31, 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@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.

Pediatric CIRB Studies

COG-AALL0434

Initial Review 2006

Documents Posted:

- Protocol Version 09/07/06
- Protocol Version 09/07/06, Highlighted Changes
- Protocol Version 07/06/06
- Protocol Version 07/06/06, Highlighted Changes
- Protocol Version 06/23/06
- Protocol Version 06/23/06, Highlighted Changes
- Protocol Version 01/09/06
- Informed Consent for Protocol Version 09/07/06: Part I - Induction Therapy
- CIRB Application Version 09/07/06
- CIRB Application Version 07/06/06
- CIRB Application Version 06/23/06
- CIRB Application Version 01/09/06
- 02/23/06: Primary Reviewer 1 Comments
- 02/23/06: Primary Reviewer 2 Comments
- 02/23/06: Primary Reviewer 3 Comments
- 02/23/06: Member 1 Comments
- 02/23/06: Pharmacist Comments
- 01/22/07: Study Activation
- 09/11/06: CIRB Approval (Protocol Version 09/07/06)
- 09/07/06: COG Response to Approval Pending Modification
- 07/31/06: Approval Pending Modification (Protocol Version 07/06/06)
- 06/23/06: COG Response to Approval Pending Modification
- 03/09/06: Approval Pending Modification (Protocol Version 01/09/06)
- 07/27/06: Group Response Meeting Minutes
- 02/23/06: Initial Review Meeting Minutes

COG-AALL06N1

Initial Review 2006

Documents Posted:

- Protocol Version 12/04/06
- Protocol Version 12/04/06, Highlighted Changes
- Informed Consent for Protocol Version 12/04/06
- CIRB Application Version 12/04/06
- CIRB Application Version 08/31/06
- 01/29/07: Study Activation



- 12/20/06: CIRB Approval (Protocol Version 12/04/06)
- 12/04/06: COG Response to Approval Pending Modification
- 11/01/06: Approval Pending Modification (Protocol Version 08/31/06)
- 08/31/06: COG Response to Approval Pending Modification

COG-ACNS0232

Initial Review 2005

Documents Posted:

- Protocol Version 09/14/06
- Protocol Version 09/14/06, Highlighted Changes
- Protocol Version 06/02/06
- Protocol Version 06/02/06, Highlighted Changes
- Protocol Version 01/04/06
- Protocol Version 01/04/06, Highlighted Changes
- Protocol Version 08/08/05
- Informed Consent for Protocol Version 09/14/06
- CIRB Application Version 09/14/06
- CIRB Application Version 06/02/06
- CIRB Application Version 01/04/06
- CIRB Application Version 08/08/05
- 02/09/06: Member 1 Comments
- 02/09/06: Member 2 Comments
- 02/09/06: Member 3 Comments
- 02/09/06: Primary Reviewer 1 Comments
- 02/09/06: Primary Reviewer 2 Comments
- 09/08/05: Member 1 Comments
- 09/08/05: Member 2 Comments
- 09/08/05: Member 3 Comments
- 09/08/05: Primary Reviewer 1 Comments
- 09/08/05: Primary Reviewer 2 Comments
- 09/08/05: Primary Reviewer 3 Comments
- 01/29/07: Study Activation
- 09/19/06: CIRB Approval (Protocol Version 09/14/06)
- 09/14/06: COG Response
- 07/24/06: COG Response to Approval Pending Modification
- 06/02/06: COG Response
- 02/24/06: CIRB Tabled Letter (Protocol Version 01/04/06)
- 01/04/06: COG Response
- 09/30/05: CIRB Tabled Letter (Protocol Version 08/08/05)
- 07/13/06: Group Response Meeting Minutes
- 02/09/06: Initial Review Meeting Minutes
- 09/08/05: Initial Review Meeting Minutes



COG-AHOD0521

Initial Review 2006
Documents Posted:

- Protocol Version 07/10/06
- Protocol Version 07/10/06, Highlighted Changes
- Protocol Version 05/08/06
- Protocol Version 05/08/06, Highlighted Changes
- Informed Consent for Protocol Version 07/10/06
- CIRB Application Version 07/10/06
- CIRB Application Version 05/08/06
- 01/12/07: Study Activation
- 07/13/06: CIRB Approval (Protocol Version 07/10/06): Study Chair
- 07/13/06: CIRB Approval (Protocol Version 07/10/06): Local IRB
- 07/10/06: COG Response to Approval Pending Modification
- 06/29/06: Approval Pending Modification (Protocol Version 05/08/06)
- 05/08/06: COG Response to Approval Pending Modification
- 06/22/06: Initial Review Meeting Minutes

Other Activity Posted:

ACOSOG-Z1031

Continuing Review (CR) December 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/09/06)
- 01/16/07: CIRB Continuing Review Approval December 2006 (Protocol Version 11/14/05)
- Protocol Version 11/14/05
- Informed Consent for Protocol Version 11/14/05 [Per Dec. 06 CR]: Main
- Informed Consent for Protocol Version 11/14/05 [Per Dec. 06 CR]: Correlative
- 12/18/06: Primary Reviewer 1 Comments
- 06/22/06: DMC Report
- 05/15/06: Study Summary

CALGB-100104-ECOG 100104

Continuing Review (CR) December 2006 [Other documents for this protocol have been included in December 29, 2006 Study Activity Update]
Documents Posted:

- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Continuing Review December 2006



CALGB-40302

Continuing Review (CR) January 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/09/06)
- 01/24/07: CIRB Continuing Review Approval January 2007 (Protocol Version 05/09/06)
- 11/01/06: Continuing Review Notice for January 2007
- Protocol Version 05/09/06
- Informed Consent for Protocol Version 05/09/06 [Per Jan. 07 CR]

CALGB-50303

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]
Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

CALGB-80101

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]
Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

CALGB-80203

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]
Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

CALGB-90202

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]
Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

CALGB-90206

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]
Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments



COG-AALL03N1

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/03/07)
- 01/10/07: CIRB Continuing Review Approval January 2007 (Protocol Version 01/03/07)
- 01/03/07: COG Response
- 12/27/06: Approval Pending Modification (Protocol Version 07/17/06)
- 10/02/06: Continuing Review Notice for January 2007
- Protocol Version 01/03/07
- Protocol Version 01/03/07, Highlighted Changes
- Informed Consent for Protocol Version 01/03/07 [Per Jan. 07 CR]

COG-AALL0434

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/07/06)
- 10/27/06: CIRB Continuing Review Approval October 2006 (Protocol Version 09/07/06)
- 10/02/06: Continuing Review Notice for October 2006
- Protocol Version 09/07/06
- Informed Consent for Protocol Version 09/07/06: Optional Pharmacokinetic
- Informed Consent for Protocol Version 09/07/06: Part I - Induction Therapy
- Informed Consent for Protocol Version 09/07/06: Part II - Low Risk
- Informed Consent for Protocol Version 09/07/06: Part II - High Risk
- Informed Consent for Protocol Version 09/07/06: Part II - Induction Failure
- Informed Consent for Protocol Version 09/07/06: Part II - Intermediate Risk

COG-ARST03P1

Amendment Review: Notice of Accrual Closure listed under the Amendment Reviews tab on the CIRB web page

Documents Posted:

- 01/12/2007: Patient Notice of Accrual Closure

ECOG-E1Y03

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments



ECOG-E1301

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/20/06: Primary Reviewer 1 Comments

ECOG-E2100

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/08/05)
- 01/10/07: CIRB Continuing Review Approval December 2006 (Protocol Version 08/08/06)
- 11/01/06: Continuing Review Notice for December 2006
- Protocol Version 08/08/05
- Informed Consent for Protocol Version 08/08/05 [Per Dec. 06 CR]
- 12/18/06: Primary Reviewer 1 Comments
- Study Progress Report Dated November 2006

ECOG-E2805

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/16/06: Primary Reviewer 1 Comments

ECOG-E3805

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/28/06)
- 01/10/07: CIRB Continuing Review Approval December 2006 (Protocol Version 07/28/06)
- 11/01/06: Continuing Review Notice for December 2006
- Protocol Version 07/28/06
- Informed Consent for Protocol Version 07/28/06 [Per Dec. 06 CR]
- 12/18/06: Primary Reviewer 1 Comments

ECOG-E3999

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments



ECOG-E4402

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

ECOG-E4599

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

ECOG-E4A03

Amendment Review: Addendum #6 (Protocol Version 10/24/06)

Documents Posted:

- Addendum #6 Cover Letter
- CIRB Application Version 10/24/06
- Summary of CIRB Application Revisions Version 10/24/06
- 12/15/06: CIRB Addendum #6 Approval (Protocol Version 10/24/06)
- Protocol Version 10/24/06
- Informed Consent for Protocol Version 10/24/06
- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06: Minutes: Addendum #6 Review

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

ECOG-E5204

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

ECOG-E6201

Continuing Review (CR) December 2006 [Other documents for this protocol have been included in December 29, 2006 Study Activity Update]

Documents Posted:



- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Continuing Review December 2006

ECOG-PACCT-1

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/20/06: Primary Reviewer 1 Comments

GOG-0212

Amendment Review: Revision #3 (Protocol Version 09/14/06) [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

GOG-0219

Continuing Review (CR) December 2006 [Other documents for this protocol have been included in December 29, 2006 Study Activity Update]

Documents Posted:

- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Continuing Review December 2006

NCCTG-N0147

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 15, 2006 Study Activity Update]

Documents Posted:

- 10/16/06: Primary Reviewer 1 Comments

NCIC CTG-MA.27

Amendment Review: Amendment #7 (Protocol Version 09/26/06) [Other documents for this protocol have been included in January 15, 2007 Study Activity Update]

Documents Posted:

- 11/20/06: Primary Reviewer 1 Comments



NCIC CTG-MA.27B

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

NSABP-B-36

Continuing Review (CR) December 2006 [Other documents for this protocol have been included in December 29, 2006 Study Activity Update]

Documents Posted:

- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Continuing Review December 2006

NSABP-B-38

Continuing Review (CR) December 2006 [Other documents for this protocol have been included in December 29, 2006 Study Activity Update]

Documents Posted:

- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Continuing Review December 2006

NSABP-C-08

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

NSABP-C-09

Continuing Review (CR) December 2006 [Other documents for this protocol have been included in January 15, 2006 Study Activity Update]

Documents Posted:

- 12/01/06: Member 1 Comments
- 12/01/06: Primary Reviewer 1 Comments
- 12/01/06, Minutes: Continuing Review December 2006

RTOG-0129

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments



RTOG-0412-SWOG-S0332

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/10/06: Primary Reviewer 1 Comments

RTOG-0415

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/23/06)
- 01/10/07: CIRB Continuing Review Approval December 2006 (Protocol Version 03/23/06)
- 11/01/06: Continuing Review Notice for December 2006
- Protocol Version 03/23/06
- Informed Consent for Protocol Version 03/23/06 [Per Dec. 06 CR]
- 12/18/06: Primary Reviewer 1 Comments
- 06/16/06: DMC Report
- Report of Studies Dated June 2006

RTOG-0421

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 15, 2006 Study Activity Update]

Documents Posted:

- 10/16/06: Primary Reviewer 1 Comments

RTOG-0525

Continuing Review (CR) October 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 10/06/06: Primary Reviewer 1 Comments

SWOG-S0012

Continuing Review (CR) November 2006 [Other documents for this protocol have been included in December 15, 2006 Study Activity Update]

Documents Posted:

- 11/20/06: Primary Reviewer 1 Comments



SWOG-S0200

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/30/04)
- 01/08/07: CIRB Continuing Review Approval January 2007 (Protocol Version 08/30/04)
- 10/03/06: Continuing Review Notice for January 2007
- Protocol Version 08/30/04 (Includes Revision #4)

SWOG-S0221

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/15/06)
- 01/10/07: CIRB Continuing Review Approval December 2006 (Protocol Version 09/15/06)
- 11/01/06: Continuing Review Notice for December 2006
- Protocol Version 09/15/06
- Informed Consent for Protocol Version 09/15/06 [Per Dec. 06 CR]
- 12/18/06: Primary Reviewer 1 Comments
- 10/19/06: DMC Report
- Toxicity Summary Dated 11/29/06
- Report of Studies Dated 10/20/06

Amendment Review: Amendment #4 (Protocol Version 09/15/06) [Other documents for this protocol have been included in November 30, 2006 Study Activity Update]

Documents Posted:

- 10/16/06: Primary Reviewer 1 Comments

SWOG-S0303

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/12/05)
- 01/08/07: CIRB Continuing Review Approval January 2007 (Protocol Version 07/12/05)
- 10/18/06: Continuing Review Notice for January 2007
- Protocol Version 07/12/05



SWOG-S0421

Continuing Review (CR) January 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/01/06)
- 01/24/07: CIRB Continuing Review Approval January 2007 (Protocol Version 06/01/06)
- Protocol Version 06/01/06
- Informed Consent for Protocol Version 06/01/06 [Per Jan. 07 CR]
- Report of Studies Dated October 2006

Serious Adverse Events

Study: CALGB-80203

SAEs Posted: 06-02-10687, 06-02-10707

Study: CALGB-80303

SAE Posted: 231325 (1)

Study: CALGB-SWOG-80405

SAEs Posted: 231325 (1), 06-02-10687, 06-02-10707

Study: CALGB-90206

SAE Posted: 231325 (1)

Study: CALGB-90401

SAE Posted: 231325 (1)

Study: ECOG E2100

SAE Posted: 231325 (1)

Study: ECOG E3200

SAE Posted: 231325 (1)

Study: ECOG E4599

SAE Posted: 231325 (1)

Study: ECOG E5202

SAE Posted: 231325 (1)

Study: ECOG E5204

SAE Posted: 231325 (1)

Study: GOG-0218

SAE Posted: 231325 (1)



Study: NSABP B-34

SAEs Posted: Safety Update # 34 FU 1, Safety Update # 38, Safety Update # 38 FU 1

Study: NSABP B-38

SAEs Posted: AU200611001243, DE200610004566, GB200611000777, KR200609000019 (1), NZ200611000483, US200606005000 (1)

Study: NSABP B-40

SAEs Posted: 229923, 229923 (2), 230490, 230490 (1), 230653, 230653 (1), 231325, 231325 (1), 232048, 233053, 233053 (1), AU200611001243, DE200608006737, DE200610000782, DE200610003194, DE200610004566, GB200611000777, KR200609000019, KR200609000019 (1), NZ200611000483, US200606005000 (1)

Study: NSABP C-08

SAEs Posted: 229923 (2), 231325 (1), 233053, 1666966

Study: RTOG 0320

SAEs Posted: 2006SP004547, 2006-04-1447

Study: RTOG 0525

SAEs Posted: 2006SP004547, 2006-04-1447

Study: SWOG S0205

SAEs Posted: DDL 240 / 06-02-10726, DDL 241 / 06-02-10707, DDL 241 / 06-02-10707 (1), DDL 242 / 06-02-10736

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.