



NCI Central IRB Study Activity Update December 29, 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 Study

CALGB-90203

Initial Review 2006 Approval

Documents Posted:

- Protocol Version 10/31/06
- Protocol Version 08/11/06
- Diet Questionnaire
- EPIC Survey
- Follow-Up Form
- Surgery and Pathology Summary
- Informed Consent for Protocol Version 10/31/06
- CIRB Application Version 10/31/06
- Summary of CIRB Application Revisions Version 10/31/06
- CIRB Application Version 08/11/06
- 10/06/06: Primary Reviewer 1 Comments
- 11/29/06: CIRB Approval (Protocol Version 10/31/06)
- 10/31/06: CALGB Response to Approval Pending Modification
- 10/24/06: Approval Pending Modification (Protocol Version 08/11/06)
- 10/06/06: Initial Review Meeting Minutes

Pediatric CIRB Study

COG-ARST0531

Initial Review 2006 Approval

Documents Posted:

- Protocol Version 05/10/06
- Protocol Version 05/10/06, Highlighted Changes
- Protocol Version 02/27/06
- Protocol Version 10/19/05
- Informed Consent for Protocol Version 05/10/06
- CIRB Application Version 05/10/06
- CIRB Application Version 02/27/06
- 01/12/06: Member 1 Comments
- 01/12/06: Member 2 Comments
- 01/12/06: Member 3 Comments
- 01/12/06: Primary Reviewer 1 Comments
- 01/12/06: Primary Reviewer 2 Comments
- 04/24/06: Pharmacist Comments
- 04/24/06: Primary Reviewer 1 Comments



- 04/24/06: Primary Reviewer 2 Comments
- 04/24/06: Primary Reviewer 3 Comments
- 05/16/06: CIRB Approval (Protocol Version 05/10/06)
- 05/16/06: CIRB Approval (Protocol Version 02/27/06)
- 02/02/06: Approval Pending Modification (Protocol Version 10/19/05)
- 05/05/06: COG Response to Approval Pending Modification
- 04/24/06: Group Response Meeting Minutes
- 01/12/06: Initial Review Meeting Minutes

Other Activity Posted:

CALGB-100104-ECOG 100104

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/23/06)
- 12/15/06: CIRB Continuing Review Approval December 2006 (Protocol Version 06/23/06)
- 10/03/06: Continuing Review Notice for December 2006
- Protocol Version 06/23/06
- Informed Consent for Protocol Version 06/23/06 [Per Dec. 06 CR]
- 06/20/06: Cover Letter
- Study Summary Dated June 2006

COG-AOST0331

Amendment Review: Amendment #1 (Protocol Version 10/31/06)

Documents Posted:

- CIRB Application Version 10/31/06
- 12/18/06: Study Activation
- 11/27/06: CIRB Amendment #1 Approval (Protocol Version 10/31/06)
- 10/31/06: COG Response to Approval Pending Modification (Protocol Version 10/31/06)
- Protocol Version 10/31/06
- Protocol Version 10/31/06, Highlighted Changes
- Informed Consent for Protocol Version 10/31/06: Part 1 - Induction Therapy
- Informed Consent for Protocol Version 10/31/06: Part 2 - Good Response
- Informed Consent for Protocol Version 10/31/06: Part 2 - Poor Response

COG-ARST0531

Amendment Review: Amendment #2 (Protocol Version 10/16/06)

Documents Posted:

- 10/17/06: Change Memo
- CIRB Application Version 10/16/06



- 12/11/06: CIRB Amendment #2 Approval (Protocol Version 10/16/06)
- Protocol Version 10/16/06
- Protocol Version 10/16/06, Highlighted Changes
- Informed Consent for Protocol Version 10/16/06

Amendment Review: Amendment #1 (Protocol Version 07/19/06)
Documents Posted:

- 07/20/06: Change Memo
- CIRB Application Version 07/19/06
- 07/31/06: CIRB Amendment #1 Approval (Protocol Version 07/19/06)
- Protocol Version 07/19/06
- Protocol Version 07/19/06, Highlighted Changes
- Informed Consent for Protocol Version 07/19/06

Continuing Review (CR) October 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/19/06)
- 10/04/06: CIRB Continuing Review Approval October 2006 (Protocol Version 07/19/06)
- 09/20/06: Continuing Review Notice for October 2006
- Protocol Version 07/19/06
- Protocol Version 07/19/06, Highlighted Changes
- Informed Consent for Protocol Version 07/19/06 [Oct. 06 CR]

ECOG-E6201

Continuing Review (CR) December 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/26/05)
- 12/15/06: CIRB Continuing Review Approval December 2006 (Protocol Version 07/26/05)
- 10/03/06: Continuing Review Notice for December 2006
- Protocol Version 07/26/05 (Per Addendum #6)
- ASCO Abstract Dated 2005
- ASCO Abstract Dated 2006
- 10/17/05: DMC Report
- 11/09/06: AE Report
- Toxicity Summary Dated June 2006

GOG-0219

Continuing Review (CR) December 2006
Documents Posted:



- CIRB Continuing Review Application (Protocol Version 06/28/06)
- 12/15/06: CIRB Continuing Review Approval December 2006 (Protocol Version 06/28/06)
- 10/03/06: Continuing Review Notice for December 2006
- Protocol Version 06/28/06
- Informed Consent for Protocol Version 06/28/06 [Per Dec. 06 CR]

NSABP-B-36

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/07/06)
- 12/15/06: CIRB Continuing Review Approval December 2006 (Protocol Version 02/07/06)
- 11/10/06: Cover Letter
- 10/03/06: Continuing Review Notice for December 2006
- Protocol Version 02/07/06
- Informed Consent for Protocol Version 02/07/06 [Per Dec. 06 CR]
- 04/07/06: DMC Report
- 11/30/05: DMC Report
- Report of Studies Dated 2005

NSABP-B-38

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 10/26/05)
- 11/10/06: Cover Letter
- 12/15/06: CIRB Continuing Review Approval December 2006 (Protocol Version 10/26/05)
- 10/03/06: Continuing Review Notice for December 2006
- Protocol Version 10/26/05 (Includes Amendment #2)
- Informed Consent for Protocol Version 10/26/05 [Per Dec. 06 CR]
- 04/07/06: DMC Report
- 11/30/05: DMC Report
- Report of Studies Dated 2005

SWOG-9007

Amendment Review: Revision #31 (Protocol Version 09/18/06)

Documents Posted:

- CIRB Application Version 09/18/06
- Summary of CIRB Application Revisions Version 09/18/06
- 10/05/06: CIRB Revision #31 Approval (Protocol Version 09/18/06)
- Protocol Version 09/18/06



- Informed Consent for Protocol Version 09/18/06

Serious Adverse Events

**Study: CALGB 80203
SAEs Posted: 229923, 1666966**

**Study: CALGB 80303
SAEs Posted: 229923, 1666966**

**Study: CALGB 90206
SAEs Posted: 229923, 1666966**

**Study: CALGB 90401
SAEs Posted: 229923, 1666966**

**Study: CALGB-SWOG 80405
SAEs Posted: 229923, 1666966**

**Study: ECOG E1302
SAEs Posted: ZD1839 (IND 61187) Investigator Notification, ZD1839 IND
Action Letter**

**Study: ECOG E2100
SAE Posted: 1666966**

**Study: ECOG E2805
SAEs Posted: 2006086148, 2006092020**

**Study: ECOG E3200
SAE Posted: 1666966**

**Study: ECOG E4599
SAE Posted: 1666966**

**Study: ECOG E5202
SAE Posted: 1666966**

**Study: ECOG E5204
SAE Posted: 1666966**

**Study: GOG 0218
SAEs Posted: 229923, 1666966**

**Study: GOG 0219
SAE Posted: 1951737**



Study: NCIC CTG MA.27
SAE Posted: MA27-16

Study: NSABP B-34
SAEs Posted: Safety Update #35, Safety Update #36, Safety Update #37

Study: NSABP B-38
SAEs Posted: Safety Update #93 FU 1, DE200610000782, DE200610003194, KR200609000019

Study: RTOG 0320
SAEs Posted: 2006-03-1739 FU 3, 2006-06-2337 FU 1, 2006-07-1249 FU 3, 2006SP002722 FU 1, 2006SP002722 FU 2, 2006SP004704 FU 1

Study: RTOG 0522
SAEs Posted: DDL 232 / 06-02-10496, DDL 238 / 06-02-10512, DDL 239 / 06-02-10687, DDL 240 / 06-02-10726, DDL 241 / 06-02-10707, DDL 241 / 06-02-10707 FU 1, DDL 242 / 06-02-10736

Study: RTOG 0525
SAEs Posted: 2006-03-1739 FU 3, 2006-06-2337 FU 1, 2006-07-1249 FU 3, 2006SP002722 FU 1, 2006SP002722 FU 2, 2006SP004704 FU 1

Study: SWOG S0124
SAE Posted: 2006097842 FU 1

Study: SWOG S0200
SAEs Posted: 20060806185 FU 2, 20061006001 FU 0

Study: SWOG S0205
SAEs Posted: DDL 232 / 06-02-10496, DDL 238 / 06-02-10512, DDL 239 / 06-02-10687

Study: SWOG S0307
SAEs Posted: 2006030074, 2006031029

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.