



NCI Central IRB Study Activity Update

March 15, 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@emmes.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@emmes.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

AAML0523

Initial Review 2006
Documents Posted:

- Protocol Version Date 06/16/06
- Protocol Version Date 06/16/06, Highlighted
- Protocol Version Date 03/14/06
- Informed Consent Form for Protocol Version Date 06/16/06
- CIRB Application Protocol Version Date 03/14/06
- CIRB Application Protocol Version Date 06/16/06
- 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
- 04/13/06: Member 1 Comments
- 06/16/06: COG Response Letter
- 06/19/06: CIRB Approval Letter (Protocol Version Date 06/16/06)
- 04/28/06: Approval Pending Modifications (Protocol Version Date 03/14/06)
- 04/13/06: Initial Review Meeting Minutes

ABTR04B1

Initial Review 2006
Documents Posted:

- Protocol Version Date 03/06/06
- Protocol Version Date 03/06/06, Highlighted
- Protocol Version Date 11/15/05
- Informed Consent Form for Protocol Version Date 03/06/06
- Informed Consent Form for Protocol Version Date 11/15/05
- CIRB Application Protocol Version Date 03/06/06
- CIRB Application Protocol Version Date 11/15/05
- 01/27/05: Member 1 Comments
- 01/27/05: Primary Reviewer 1 Comments
- 01/27/05: Pharmacist Comments
- 01/27/05: Primary Reviewer 2 Comments



- 01/27/05: Primary Reviewer 3 Comments
- 03/28/06: Approval Letter for Protocol Version Date 03/06/06
- 03/09/06: CIRB Final Approval Letter: Local Chair (Protocol Version Date 03/06/06)
- 03/09/06: CIRB Final Approval Letter: Study Chair (Protocol Version Date 03/06/06)
- 03/06/06: Response to CIRB Approval Pending Modification to Initial Review
- 02/06/06: CIRB Approval Pending Modification to Initial Review
- 11/15/05: Group Response Letter
- 01/26/06: Initial Review Meeting Minutes

Other Activity Posted:

AAML0523

Amendment Review (AR): Amendment #2 (Protocol Version Date 01/12/07)
Documents Posted:

- CIRB Application Protocol Version Date 01/12/07
- 01/14/07: COG Response Letter
- Protocol Version Date 01/12/07
- Protocol Version Date 01/12/07, Highlighted
- Informed Consent Form for Protocol Version Date 01/12/07

Continuing Review (CR) January 2007 Approval
Documents Posted:

- CIRB Application Protocol Version Date 06/16/06
- 01/12/07: Continuing Review Approval Letter
- 12/01/06: Continuing Review Notice Letter
- Protocol Version Date 06/16/06
- Protocol Version Date 06/16/06, Highlighted
- Informed Consent Form for Protocol Version Date 06/16/06

ABTR04B1

Amendment Review (AR): Amendment #1 (Protocol Version Date 05/13/06)
Documents Posted:

- 05/13/06: Change Memo
- CIRB Application for Protocol Version Date 05/13/06
- 06/05/06: CIRB Amendment #1 Approval (Protocol Version Date 05/13/06)



- 06/05/06: CIRB Amendment #1 Approval to Local IRB Chair (Protocol Version Date 05/13/06)
- Protocol Version Date 05/13/06
- Protocol Version Date 05/13/06, Highlighted
- Informed Consent Form for Protocol Version Date 05/13/06

Amendment Review (AR): Amendment #2 (Protocol Version Date 02/06/07)
Documents Posted:

- 12/10/06: Change Memo
- CIRB Application Protocol Version Date 02/06/07
- CIRB Application Protocol Version Date 12/10/06
- 02/20/07: CIRB Amendment #2 Approval (Protocol Version Date 02/06/07)
- 02/06/07: Response to Approval Pending Modification (Protocol Version Date 12/10/06)
- Protocol Version Date 02/06/07
- Protocol Version Date 02/06/07, Highlighted
- Protocol Version Date 12/10/06
- Informed Consent Form for Protocol Version Date 02/06/07

Continuing Review (CR) November 2006 Approval
Documents Posted:

- CIRB Application Protocol Version Date 05/13/06
- 11/27/06: CIRB Continuing Review Approval (Protocol Version 05/13/06)
- Protocol Version Date 05/13/06
- Protocol Version Date 05/13/06, Highlighted
- Informed Consent Form for Protocol Version Date 05/13/06

ACNS0423

Amendment Review (AR): Amendment #2 (Protocol Version Date 02/12/07)
Documents Posted:

- CIRB Application for Protocol Version Date 02/12/07
- CIRB Application for Protocol Version Date 11/15/06
- 02/20/07: Letter of Approval
- 02/13/07: COG Response Letter
- 01/02/07: CIRB Approval Pending Modification Letter
- 11/16/06: COG Response Letter
- Protocol Version Date 02/12/07
- Protocol Version Date 02/12/07, Highlighted
- Protocol Version Date 11/15/06
- Protocol Version Date 11/15/06, Highlighted



- Informed Consent Form for Protocol Version Date 02/12/07
- Informed Consent Form for Protocol Version Date 11/15/06
- 12/14/06: Member 1 Comments
- 12/14/06: Primary Reviewer 1 Comments

AREN0532

Continuing Review (CR) January 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/23/07)
- 03/09/07: CIRB Continuing Approval Letter (Protocol Version Date 02/23/07)
- 02/23/07: COG Response
- 01/29/07: Approval Pending Modification (Protocol Version Date 02/23/07)
- Protocol Version Date 02/23/07
- Informed Consent Form for Protocol Version Date 02/23/07: Chemotherapy Arm
- Informed Consent Form for Protocol Version Date 02/23/07: Observation Arm

AREN0533

Continuing Review (CR) February 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/17/06)
- 03/02/07: CIRB Continuing Review Approval Letter (Protocol Version Date 10/17/06)
- Protocol Version Date 10/17/06
- Informed Consent for Protocol Version Date 10/17/06

CALGB-10201

Continuing Review (CR) February 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/29/05)
- 03/01/2007: CIRB Continuing Review Approval Letter February 2007 (Protocol Version Date 06/29/05)



CALGB-90206

Amendment Review (AR): Update #7 (Protocol Version 08/29/06)

Documents Posted:

- CIRB Application Revisions Summary (Protocol Version Date 08/29/06)
- 10/15/06: Change Memo
- CIRB Application (Protocol Version 8/29/06)
- 12/15/06: CIRB Approval Letter for Update #7
- 10/24/06: Approval Pending Modification (Protocol Version Date 08/29/06)
- Protocol Version Date 10/26/06
- Protocol Version Date 08/29/06
- 12/01/06: Primary Reviewer 1 Comments
- 10/06/06: Primary Reviewer 1 Comments
- 12/01/06: Minutes: Amendment Review

CALGB-SWOG C80405

Continuing Review (CR) February 2007 Approval

Documents Posted:

- Continuing Review February 2007: Group Continuing Review Application
- 02/28/07: Continuing Review February 2007: CIRB Approval Letter
- Protocol Version 05/22/06
- Informed Consent for Protocol Version Date 5/22/06 [per February 2007 CR]

ECOG-E1A00

Continuing Review (CR) January 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/30/05)
- 03/05/07: CIRB Continuing Review Approval Letter (Protocol Version Date 12/30/05)

ECOG-E1Y03

Amendment Review (AR): Addendum #4 (Protocol Version Date 11/15/06)

Documents Posted:

- 11/15/06: Addendum #4
- Summary of CIRB Application Revisions
- CIRB Application for Protocol Version Date 11/15/06
- 01/11/07: Addendum Review Approval
- 01/10/07: Approval Letter
- Protocol Version Date 11/15/06
- Informed Consent Form for Protocol Version Date 11/15/06



- 12/18/06: Primary Reviewer 1 Comments

ECOG-E2902

Continuing Review (CR) February 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/25/06)
- 03/01/07: Continuing Review February 2007: CIRB Approval Letter
- Informed Consent for Protocol Version 05/25/06 [per February 2007 CR]

NSABP-B-40

Continuing Review (CR) February 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/18/06)
- 03/01/07: Continuing Review February 2007: CIRB Approval Letter
- Informed Consent for Protocol Version Date 08/18/06 [per February 2007 CR]

RTOG- 0126

Continuing Review (CR) January 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/18/06)
- 03/05/06: CIRB Continuing Review Approval Letter (Protocol Version Date 04/18/06)
- Informed Consent for Protocol Version Date 04/18/06 [per Jan 2007 CR]

SWOG- S0205

Continuing Review (CR) January 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/03/06)
- 03/05/07: CIRB Continuing Review Approval Letter (Protocol Version Date 01/03/06)

SWOG- S0500

Amendment Review (AR): Revision #1 (Protocol Version Date 11/21/06)
Documents Posted:

- CIRB Application Protocol Version Date 11/21/06
- 01/24/07: Approval Letter
- Protocol Version Date 11/21/06
- Informed Consent Form for Protocol Version Date 11/21/06



SWOG- S9925

Amendment Review (AR): Revision #10 (Protocol Version Date 12/13/06)
Documents Posted:

- CIRB Application Protocol Version Date 12/13/06
- 02/01/07: CIRB Approval Letter
- Protocol Version Date 12/13/06

Serious Adverse Events

**Study: CALGB-80303
SAE Posted: 1133478**

**Study: CALGB-90206
SAE Posted: 1133478**

**Study: CALGB-90401
SAE Posted: 1133478**

**Study: CALGB-SWOG-80405
SAE Posted: 1133478**

**Study: NCIC CTG MA.27
SAE Posted: 10000169**

**Study: NSABP B-34
SAEs Posted: Safety Update #39, Safety Update #40, Safety Update #40 (1),
Safety Update #41, Safety Update #42**

**Study: NSABP B-38
SAEs Posted: GB200605003173, US_0404102176**

**Study: NSABP B-40
SAEs Posted: 234306, GB200605003173, US_0404102176**

**Study: SWOG S0023
SAE Posted: 1352930**

**Study: SWOG S0307
SAEs Posted: 2006027512 (1), 2006032513, 2006036528, 2006036528 (1),
2006040021, 2006040021 (1), 2006040116, 2007000323**



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@emmes.com.