



NCI Central IRB Study Activity Update

January 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@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 study listed below has received CIRB approval and is 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 Study

COG-AHOD04B1

Initial Review 2006 [Other documents for this protocol have been included in November 1, 2006 Study Activity Update]

Documents Posted:

- 06/08/06: Pharmacist Comments
- 06/08/06: Primary Reviewer 1 Comments
- 06/08/06: Primary Reviewer 2 Comments
- 06/08/06: Primary Reviewer 3 Comments

Other Activity Posted:

CALGB-40101

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

CALGB-70301

Amendment Review: Update #2 (Protocol Version 07/07/06) [Other documents for this protocol have been included in November 30, 2006 Study Activity Update]

Document Posted:

- 08/21/06: Minutes: Update #2 Review

CALGB-80303

Amendment Review: Update #6 (Protocol Version 06/20/06) [Other documents for this protocol have been included in November 30, 2006 Study Activity Update]

Document Posted:

- 09/18/06: 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]

Document Posted:

- 11/10/06, Minutes: Continuing Review November 2006



COG-AREN0321

Amendment Review: Amendment #2 (Protocol Version 11/20/06)
Documents Posted:

- 11/20/06: Change Memo
- CIRB Application Version 11/20/06
- 12/11/06: CIRB Amendment #2 Approval (Protocol Version 11/20/06)
- Protocol Version 11/20/06
- Protocol Version 11/20/06, Highlighted Changes
- Informed Consent for Protocol Version 11/20/06: Regimen DD-4A
- Informed Consent for Protocol Version 11/20/06: Observation
- Informed Consent for Protocol Version 11/20/06: Regimen I
- Informed Consent for Protocol Version 11/20/06: Regimen UH1
- Informed Consent for Protocol Version 11/20/06: Window Therapy

ECOG-E1899

Continuing Review (CR) January 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/16/04)
- 01/09/07: CIRB Continuing Review Approval January 2007 (Protocol Version 06/16/04)
- 10/03/06: Continuing Review Notice for January 2007
- Protocol Version 06/16/04
- 11/02/04: DMC Report
- Report of Studies Dated June 2005

ECOG-E1900

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]
Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

ECOG-E2805

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

- 06/29/06: Change Memo
- CIRB Application Version 10/16/06
- CIRB Application Version 06/29/06
- Summary of CIRB Application Revisions Version 10/16/06
- Summary of CIRB Application Revisions Version 06/29/06
- 11/08/06: CIRB Addendum #2 Approval (Protocol Version 10/16/06)



- 10/16/06: ECOG Response to Approval Pending Modification (Protocol Version 10/16/06)
- 09/08/06: Approval Pending Modification (Protocol Version 06/29/06)
- Protocol Version 10/16/06
- Informed Consent for Protocol Version 10/16/06

GOG-0198

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

GOG-0204

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

GOG-0209

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

NCIC CTG-BR.19

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/03/05)
- 12/28/06: CIRB Continuing Review Approval December 2006 (Protocol Version 01/03/05)
- 09/11/06: Continuing Review Notice for December 2006
- Protocol Version 01/03/05
- Report of Studies Dated 02/24/06

NCIC CTG-MA.27

Amendment Review: Amendment #7 (Protocol Version 09/29/06)

Documents Posted:

- 09/26/06: Change Memo
- CIRB Application Version 09/26/06
- Summary of CIRB Application Revisions Version 09/26/06



- 12/12/06: CIRB Amendment #7 Approval (Protocol Version 09/26/06)
- Protocol Version 09/26/06
- Informed Consent for Protocol Version 09/26/06

NSABP-C-09

Continuing Review (CR) December 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 10/05/05)
- 01/02/07: CIRB Continuing Review Approval December 2006 (Protocol Version 10/05/05)
- 12/29/06: NSABP Response
- 12/28/06: Approval Pending Modification (Protocol Version 10/05/05)
- 10/03/06: Continuing Review Notice for December 2006
- Protocol Version 10/05/05
- Informed Consent for Protocol Version 10/05/05 [Per Dec. 06 CR]

RTOG-0421

Amendment Review: Amendment #1 (Protocol Version 09/19/06) [Other documents for this protocol have been included in November 15, 2006 Study Activity Update]

Document Posted:

- 09/01/06: Primary Reviewer 1 Comments

RTOG-0521

Amendment Review: Amendment #1 (Protocol Version 10/04/06) [Other documents for this protocol have been included in November 30, 2006 Study Activity Update]

Document Posted:

- 09/01/06: Primary Reviewer 1 Comments

SWOG-9007

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

SWOG-S0023

Continuing Review (CR) December 2006

Document Posted:

- CIRB Continuing Review Application (Protocol Version 06/29/05)



- 12/08/06: CIRB Continuing Review Approval December 2006 (Protocol Version 06/29/05)
- 09/11/06: Continuing Review Notice for December 2006
- Protocol Version 06/29/05 (Includes revision #14)
- Report of Studies Dated 10/13/06

SWOG-S0106

Amendment Review: Revision #4 (Protocol Version 08/09/06) [Other documents for this protocol have been included in November 15, 2006 Study Activity Update]
Documents Posted:

- 09/18/06: Primary Reviewer 1 Comments
- 09/18/06: Primary Reviewer 2 Comments

SWOG-S0124

Amendment Review: Amendment #2 (Protocol Version 09/29/06)
Documents Posted:

- CIRB Application Version 09/29/06
- Summary of CIRB Application Revisions Version 09/29/06
- 12/12/06: CIRB Amendment #2 Approval (Protocol Version 09/29/06)
- Protocol Version 09/29/06
- Informed Consent for Protocol Version 09/29/06
- 11/20/06: Primary Reviewer 1 Comments

SWOG-S0309

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]
Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

SWOG-S9910

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]
Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

SWOG-S9925

Amendment Review: Amendment #15 (Protocol Version 10/13/06)
Documents Posted:

- CIRB Application Version 10/13/06
- Summary of CIRB Application Revisions Version 10/13/06



- 12/12/06: CIRB Amendment #15 Approval (Protocol Version 10/13/06)
- Protocol Version 10/13/06

Continuing Review (CR) September 2006 [Other documents for this protocol have been included in October 16, 2006 Study Activity Update]

Document Posted:

- 09/18/06: Primary Reviewer 1 Comments

Serious Adverse Events

Study: COG-ADVL0524
SAE Posted: 1683941

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.