



NCI Central IRB Study Activity Update November 15, 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

NSABP-B-40

Initial Review 2005

Documents Posted:

- Protocol Version 08/25/05
- Protocol Version 05/06/05
- Informed Consent for Protocol Version 08/25/05
- CIRB Application Version 05/06/05
- 07/18/05: Primary Reviewer 1 Comments
- 07/18/05: Primary Reviewer 2 Comments
- 10/07/05: Primary Reviewer 1 Comments
- 10/07/05: Primary Reviewer 2 Comments
- 10/13/05: CIRB Approval (Protocol Version 08/25/05): Local IRB
- 10/13/05: CIRB Approval (Protocol Version 08/25/05): Study Chair
- 08/25/05: NSABP Response to Approval Pending Modification
- 08/08/05: Approval Pending Modification (Protocol Version 05/06/05)
- 07/18/05: Initial Review Meeting Minutes

Other Activity Posted:

COG-ACNS0224

Continuing Review (CR) November 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/14/05)
- 11/07/06: CIRB Continuing Review Approval November 2006 (Protocol Version 07/14/05)
- 10/06/06: Approval Pending Modification (Protocol Version 07/14/05)
- 06/27/06: Continuing Review Notice for November 2006
- Protocol Version 07/14/05
- Informed Consent for Protocol Version 07/14/05 [Per Nov. 06 CR]: Phase I
- Informed Consent for Protocol Version 07/14/05 [Per Nov. 06 CR]: Phase II
- 09/28/06, Minutes: Continuing Review November 2006
- 03/29/06: DSMC Report
- Study Progress Report Dated 09/05/06

COG-AHOD0431

Continuing Review (CR) October 2006

Documents Posted:



- CIRB Continuing Review Application (Protocol Version 10/19/05)
- 11/01/06: CIRB Continuing Review Approval October 2006 (Protocol Version 10/19/05)
- 09/20/06: Continuing Review Notice for October 2006
- Protocol Version 10/19/05
- Informed Consent for Protocol Version 10/19/05 [Per Oct. 06 CR]: Initial Treatment
- Informed Consent for Protocol Version 10/19/05 [Per Oct. 06 CR]: Relapse Treatment
- Study Progress Report Dated 09/05/06

ECOG-E2805

Amendment Review: Addendum #1 (Protocol Version 06/14/06)

Documents Posted:

- CIRB Application Version 06/14/06
- Summary of CIRB Application Revisions Version 06/14/06
- 06/16/06: CIRB Addendum #1 Approval (Protocol Version 06/14/06): Study Chair
- 06/16/06: CIRB Addendum #1 Approval (Protocol Version 06/14/06): Local IRB
- 06/14/06: ECOG Response to Approval Pending Modification
- 06/12/06: Approval Pending Modification (Protocol Version 04/27/06)
- Protocol Version 06/14/06
- Informed Consent for Protocol Version 06/14/06

ECOG-E5202

Amendment Review: Addendum #7 (Protocol Version 08/24/06)

Documents Posted:

- 08/24/06: Change Memo
- CIRB Application Version 06/23/06
- Summary of CIRB Application Revisions Version 06/23/06
- 09/11/06: CIRB Addendum #7 Approval (Protocol Version 08/24/06)
- 08/24/06: ECOG Response to Approval Pending Modification (Protocol Version 08/24/06)
- 08/21/06: Approval Pending Modification (Protocol Version 06/23/06)
- Protocol Version 08/24/06
- Informed Consent for Protocol Version 08/24/06
- 08/04/06: Primary Reviewer 1 Comments
- 08/04/06, Minutes: Addendum #7 Review

ECOG-E5204

Amendment Review: Addendum #1 (Protocol Version 08/24/06)

Documents Posted:



- 08/24/06: Change Memo
- CIRB Application Version 06/23/06
- Summary of CIRB Application Revisions Version 06/23/06
- 09/11/06: CIRB Addendum #1 Approval (Protocol Version 08/24/06)
- 08/24/06: ECOG Response to Approval Pending Modification (Protocol Version 06/23/06)
- 08/21/06: Approval Pending Modification (Protocol Version 06/23/06)
- Protocol Version 08/24/06
- Informed Consent for Protocol Version 08/24/06

NCCTG-N0147

Continuing Review (CR) October 2006

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 06/28/05)
- 11/07/06: CIRB Continuing Review Approval October 2006 (Protocol Version 06/28/05)
- 09/11/06: Continuing Review Notice for October 2006
- Protocol Version 06/28/05 (Part 1)
- Protocol Version 06/28/05 (Part 2)
- Protocol Version 06/28/05 (Part 3)
- Protocol Version 06/28/05 (Part 4)
- Protocol Version 06/28/05 (Part 5)
- Protocol Version 06/28/05 (Part 6)
- Protocol Version 06/28/05 (Part 7)
- Informed Consent for Protocol Version 06/28/05 [Per Oct. 06 CR]: Six-Arm Randomization
- Informed Consent for Protocol Version 06/28/05 [Per Oct. 06 CR]: Two-Arm Randomization
- Report of Studies
- 04/11/06: DMC Report

NSABP-B-40

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

Documents Posted:

- 08/18/06: Change Memo
- CIRB Application Version 08/18/06
- Summary of CIRB Application Revisions Version 08/18/06
- 10/05/06: CIRB Revision #6 Approval (Protocol Version 08/18/06)
- Protocol Version 08/18/06
- Informed Consent for Protocol Version 08/18/06



Amendment Review: Pre-Activation Amendment #2 (Protocol Version 05/11/06)
Documents Posted:

- 05/11/06: Change Memo
- CIRB Application Version 05/11/06
- Summary of CIRB Application Revisions Version 05/11/06
- 06/21/06: CIRB Pre-Activation Amendment #2 Approval (Protocol Version 05/11/06): Local IRB
- 06/21/06: CIRB Pre-Activation Amendment #2 Approval (Protocol Version 05/11/06): Study Chair
- Protocol Version 05/11/06
- Informed Consent for Protocol Version 05/11/06
- 06/19/06: Minutes: Pre-Activation Amendment #2 Review

Continuing Review (CR) April 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 08/25/05)
- 04/17/06: CIRB Continuing Review Approval April 2006 (Protocol Version 08/25/05): Local IRB
- 04/17/06: CIRB Continuing Review Approval April 2006 (Protocol Version 08/25/05): Study Chair
- 03/07/06: Continuing Review Notice for April 2006
- Protocol Version 08/25/05
- Informed Consent for Protocol Version 08/25/05 [Per April 06 CR]

RTOG-0421

Continuing Review (CR) October 2006
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/11/05)
- 08/08/06: Continuing Review Notice for October 2006
- 11/07/06: CIRB Continuing Review Approval October 2006 (Protocol Version 09/19/06)
- Protocol Version 09/19/06
- Informed Consent for Protocol Version 09/19/06
- Report of Studies
- 06/16/06: DMC Minutes

Amendment Review: Amendment #1 (Protocol Version 09/19/06)
Documents Posted:

- 09/19/06: Change Memo



- CIRB Application Version 09/19/06
- Summary of CIRB Application Revisions Version 09/19/06
- 09/28/06: CIRB Amendment #1 Approval (Protocol Version 09/19/06)
- 09/19/06: RTOG Response to Approval Pending Modification (Protocol Version 09/19/06)
- 09/06/06: Approval Pending Modification (Protocol Version 07/14/06)
- 07/14/06: RTOG Response to Approval Pending Modification (Protocol Version 07/14/06)
- 05/24/06: Approval Pending Modification (Protocol Version 04/14/06)
- Protocol Version 09/19/06
- Informed Consent for Protocol Version 09/19/06
- 05/15/06, Minutes: Amendment #1 Review

SWOG-S0106

Amendment Review: Revision #4 (Protocol Version 08/09/06)

Documents Posted:

- CIRB Application Version 08/09/06
- Summary of CIRB Application Revisions Version 08/09/06
- 09/27/06: CIRB Revision #4 Approval (Protocol Version 08/09/06)
- Protocol Version 08/09/06
- Informed Consent for Protocol Version 08/09/06

SWOG-S0232

Amendment Review: Amendment #3 (Protocol Version 05/25/06)

Documents Posted:

- CIRB Application Version 05/25/06
- Summary of CIRB Application Revisions Version 05/25/06
- 09/25/06: CIRB Amendment #3 Approval (Protocol Version 05/25/06)
- 06/09/06: Approval Pending Modification (Protocol Version 05/25/06)
- Protocol Version 05/25/06
- Informed Consent for Protocol Version 05/25/06
- 05/15/06, Minutes: Amendment #3 Review

SWOG-S9910

Amendment Review: Revision #12 (Protocol Version 07/20/06)

Documents Posted:

- CIRB Application Version 07/20/06
- Summary of CIRB Application Revisions Version 07/20/06
- 08/21/06: CIRB Revision #12 Approval (Protocol Version 07/20/06)
- Protocol Version 07/20/06
- Informed Consent for Protocol Version 07/20/06



Serious Adverse Events

Study: None

SAE Posted: There are no SAEs to report in this Activity Update.

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.