



NCI Central IRB Study Activity Update

February 28, 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

COG-AREN0533

Initial Review 2006

Documents Posted:

- Protocol Version Date 06/19/06
- Protocol Version Date 06/19/06, Highlighted Changes
- Protocol Version Date 03/07/06
- Informed Consent Form for Protocol Version 06/19/06
- CIRB Application (Protocol Version Date 06/19/06)
- CIRB Application (Protocol Version Date 03/07/06)
- 04/13/06: Primary Reviewer 1 Comments
- 04/13/06: Primary Reviewer 2 Comments
- 04/13/06: Primary Reviewer 3 Comments
- 04/13/06: Pharmacist Comments
- 06/29/06: CIRB Final Approval Letter
- 06/20/06: CIRB Response Letter
- 04/28/06: CIRB Approval Pending Modification to Initial Review
- 04/13/06: Initial Review Meeting Minutes

Other Activity Posted:

COG-ANBL00P3

Continuing Review (CR) December 2006 Approval

Documents Posted:

- 02/01/07: CIRB Continuing Review Application
- 11/20/06: CIRB Continuing Review Application
- 02/06/07, Approval (Protocol Version Date 01/31/07)
- 01/31/07: Group Response Letter
- 12/21/06: Approval Pending Modification (Protocol Version Date 07/26/05)
- Continuing Review Reminder Notice
- Protocol Version Date 01/31/07
- Protocol Version Date 01/31/07, Highlighted
- Protocol Version Date 07/26/05
- Informed Consent (High and Intermediate Risk) for Protocol Version 01/31/07 [Per Dec. 06 CR]
- Informed Consent (Low Risk) for Protocol Version 01/31/07 [Per Dec. 06 CR]
- Informed Consent (Low Risk) for Protocol Version 07/26/05



- Informed Consent (High and Intermediate Risk) for Protocol Version 07/26/05
- 10/09/06: DSMC Letter

COG-AREN0533

Amendment Review (AR): Amendment #1 (Protocol Version 10/17/06)

Documents Posted:

- CIRB Application (Protocol Version Date 10/17/06)
- 11/09/06: Expedited Review Amendment #1 Approval Letter (Protocol Version Date 10/17/06)
- 10/17/06: COG Response to Protocol Modifications
- Protocol Version Date 10/17/06

Amendment Review (AR): Amendment #2 (Protocol Version 11/14/06)

Documents Posted:

- CIRB Application (Protocol Version Date 11/14/06)
- 02/26/07: COG Letter - Activation of Study
- 02/12/07: Expedited Review Amendment #2 Approval Letter (Protocol Version Date 11/14/06)
- 11/14/06: COG Response to Second Activation Amendment
- Protocol Version Date 11/14/06
- Protocol Version Date 11/14/06, Highlighted Changes
- Informed Consent Form for Protocol Version Date 11/14/06

ECOG – E3805

Amendment Review (AR) December 2006 Approval

Documents Posted:

- CIRB Application Version 10/13/06
- 12/15/06: CIRB Approval to Addendum #2 (Protocol Version Date 10/13/06)
- 10/13/06: ECOG Response
- Protocol Version Date (10/13/06)
- Informed Consent for Protocol Version Date 10/13/06
- 12/15/06: Primary Reviewer 1 Comments
- 12/01/06: Minutes: Addendum #2 Review



GOG 0218

Continuing Review (CR) January 2007 Approval
Documents Posted:

- Continuing Review January 2007: Group Continuing Review Application
- 02/16/07, Continuing Review January 2007 - Approval (Version 05/12/06)
- 11/01/06, Notification of Continuing Review January 2007
- Protocol, Version 05/12/06
- Informed Consent for Protocol Version 05/12/06 [per January 2007 CR]
- DSMC Minutes, July 22, 2006

SWOG S0232

Continuing Review (CR) January 2007 Approval
Documents Posted:

- Continuing Review January 2007: Group Continuing Review Application
- 02/16/07, Continuing Review January 2007 - Approval (Version 10/03/06)
- 02/16/07, Continuing Review January 2007 - Group Response
- 02/01/07, Continuing Review January 2006 - Approval Pending Modifications
- Protocol Version 10/03/06
- Informed Consent for Protocol Version 10/03/06 [per January 2007 CR]
- 10/19/06, DSMC Meeting Minutes
- 10/5-8/06, Report of Studies

Serious Adverse Events

Study: NONE
SAE Posted: NONE

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.