



NCI Central IRB Protocol Activity Update August 31, 2006

The CIRB is distributing this protocol 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. ******

Adult CIRB Studies

ECOG-E2603

Continuing Review August 2006
Documentation posted:



- CIRB Continuing Review Application Version 06/26/06
- 08/28/06, CIRB Approval to Continuing Review August 2006 (Protocol Version 10/17/05)
- 05/11/06, Notification of Continuing Review July 2006
- Protocol Version 10/17/05
- Informed Consent for Protocol Version 10/17/05 [per Aug 2006 CR]
- Study Summary

ECOG-PACCT-1

Amendment Review: Addendum #1 (Protocol Version 06/13/06)

Documentation posted:

- 06/13/06, Change Memo
- CIRB Application Version 06/13/06
- Summary of CIRB Application Revisions Version 06/13/06
- 08/09/06, CIRB Approval to Addendum #1 (Protocol Version 06/13/06)
- Protocol Version 06/13/06
- Informed Consent for Protocol Version 06/13/06

NCCTG-N0434 (MA.27D)

Continuing Review August 2006

Documentation posted:

- CIRB Continuing Review Application Version 02/01/06
- 08/21/06, CIRB Approval to Continuing Review August 2006 (Protocol Version 02/01/06)
- Informed Consent for Protocol Version 02/01/06 (Per Aug. 06 CR)

SWOG-S0307

Amendment Review: Revision #1 (Protocol Version 06/12/06)

Documentation posted:

- CIRB Application Version 06/12/06
- Summary of CIRB Application Revisions Version 06/12/06
- 07/17/06: CIRB Approval (Protocol Version 06/12/06)
- 06/12/06: SWOG Response to Tabled Action 2 (Protocol Version 04/14/06)
- 03/29/06: CIRB Table Letter 1 (Protocol Version 02/02/06)
- 05/12/06: CIRB Table Letter 2 (Protocol Version 04/14/06)
- 04/14/06: SWOG Response to Tabled Action 1 (Protocol Version 02/02/06)
- Protocol Version 06/12/06
- Informed Consent for Protocol Version 06/12/06
- 03/20/06: Primary Reviewer 1 Comments
- 05/05/06: Meeting Minutes

SWOG-S9925



Amendment Review: Amendment #14 (Protocol Version 07/25/06)
Documentation posted:

- CIRB Application Version 07/25/06
- Summary of CIRB Application Revisions Version 07/25/06
- 08/07/06: CIRB Approval (Protocol Version 07/25/06)
- Protocol Version 07/25/06

Pediatric CIRB Studies

COG-AOST0331

Continuing Review August 2006
Documentation posted:

- CIRB Continuing Review Application Version 07/19/06
- 08/10/06, CIRB Approval to Continuing Review August 2006 (Protocol Version 09/13/05)
- Informed Consent for Protocol Version 09/13/05: Part 1 [Per Sep. 05 CR]: Induction Therapy
- Informed Consent for Protocol Version 09/13/05: Part 2 [Per Sep. 05 CR]: Good Response
- Informed Consent for Protocol Version 09/13/05: Part 2 [Per Sep. 05 CR]: Poor Response

COG-AREN0321

Amendment Review: Amendment #1 (Protocol Version 08/08/06)
Documentation posted:

- 08/08/06, Change Memo
- CIRB Application Version 08/08/06
- 08/21/06: CIRB Approval to Amendment #1 (Protocol Version 08/08/06)
- Protocol Version 08/08/06, Highlighted Changes
- Protocol Version 08/08/06
- Informed Consent for Protocol Version 08/08/06: Regimen UH1
- Informed Consent for Protocol Version 08/08/06: Regimen DD-4A
- Informed Consent for Protocol Version 08/08/06: Regimen I
- Informed Consent for Protocol Version 08/08/06: Window Therapy
- Informed Consent for Protocol Version 08/08/06: Observation

COG-ARST0431

Amendment Review: Amendment #1 (Protocol Version 08/03/06)
Documentation posted:

- 08/03/06, Change Memo
- CIRB Application Version 08/03/06



- 08/22/06: CIRB Approval to Amendment #1 (Protocol Version 08/03/06)
- Protocol Version 08/03/06
- Protocol Version 08/03/06, Highlighted Changes
- Informed Consent for Protocol Version 08/03/06

Serious Adverse Events

Study: Study Number

SAE Posted: There are no SAE 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.