



NCI Central IRB Protocol Activity Update July 18, 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. **

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-ARST0431

Initial Review 2005

Documentation posted:

- Protocol Version 03/09/06
- Protocol Version 03/09/06, Highlighted Changes
- Protocol Version 10/24/05
- Informed Consent for Protocol Version 03/09/06
- CIRB Application Version 03/09/06
- CIRB Application Version 10/24/05
- 12/08/05: Primary Reviewer 1 Comments
- 12/08/05: Primary Reviewer 3 Comments
- 12/08/05: Primary Reviewer 2 Comments
- 12/08/05: Pharmacist Comments
- 12/08/05: Member 1 Comments
- 12/08/05: Member 2 Comments
- 12/08/05: Member 3 Comments
- 12/08/05: Member 4 Comments
- 01/09/06: COG Protocol Disparities between ARST0431 and ARST0332
- 01/04/06: Approval Pending Modification (Protocol Version 10/24/05)
- 03/11/06: COG Response to Approval Pending Modification
- 03/15/06: CIRB Approval (Protocol Version 03/09/06): Local IRB
- 12/08/05: Initial Review Meeting Minutes

Amendment Review: Update #1 (Protocol Version 05/12/06)

Documentation posted:

- 05/12/06, Change Memo
- PedCIRB Application Version 05/12/06
- 05/31/06: CIRB Approval (Protocol Version 05/12/06): Local IRB
- 05/31/06: CIRB Approval (Protocol Version 05/12/06): Study Chair
- Protocol Version 05/12/06
- Protocol Version 05/12/06, Highlighted Changes
- Informed Consent for Protocol Version 05/12/06

Other Activity Posted:

ACOSOG Z9031

Permanent Closure Notice [see Amendment Review section]

Documentation posted:

- 02/27/06: Notification from ACOSOG of Permanent Closure
- 06/09/06: CIRB's Acknowledgement of Closure



CALGB 30102

Continuing Review July 2006
Documentation posted:

- 07/14/06: Continuing Review Application July 2006
- 07/13/06: CIRB Approval (Protocol Version 08/07/03): Study Chair
- 07/13/06, CIRB Approval (Protocol Version 08/07/03): Local IRB
- Protocol Version 08/07/03
- Informed Consent for Protocol Version 08/07/03
- Study Summary June 2005

CALGB 50303

Amendment Review: Update #2 (Protocol Version 03/27/06)
Documentation posted:

- Update #2 (Protocol Version 03/27/06)
- CIRB Application Version 03/27/06
- CIRB Summary of Application Revisions (Protocol Version 03/27/06)
- 05/12/06: CIRB Approval (Protocol Version 03/27/06): Study Chair
- 05/12/06: CIRB Approval (Protocol Version 03/27/06): Local IRB
- Protocol Version 03/27/06
- Informed Consent for Protocol Version 03/27/06
- 05/05/06: Update #2 Meeting Minutes

CALGB 80303

Amendment Review: Update #5 (Protocol Version 03/01/06)
Documentation posted:

- 03/01/06, Change Memo
- CIRB Application Version 03/01/06
- 06/05/06: CIRB Approval (Protocol Version 03/01/06): Local IRB
- 06/09/06: CIRB Approval (Protocol Version 03/01/06): Study Chair
- Protocol Version 03/01/06
- Informed Consent for Protocol Version 03/01/06

CALGB-SWOG-C80405

Amendment Review: Update #2 (Protocol Version 05/22/06)
Documentation posted:

- 05/22/06, Change Memo
- CIRB Application Version 05/22/06
- Summary of Revision to CIRB Application Version 05/22/06
- 06/21/06, CIRB Approval (Protocol Version 05/22/06): Local IRB
- 06/21/06, CIRB Approval (Protocol Version 05/22/06): Study Chair
- Protocol Version 05/22/06



- Informed Consent for Protocol Version 05/22/06

CALGB-100104-ECOG 100104

Amendment Review: Update #4 (Protocol Version 06/23/06)

Documentation posted:

- 06/23/06, Change Memo
- CIRB Application Version 06/23/06
- Summary of CIRB Application Revisions (Protocol Version 06/23/06)
- 06/26/06, Approval to Update #4 (Protocol Version 06/23/06): Study Chair
- 06/26/06, Approval to Update #4 (Protocol Version 06/23/06): Local IRB
- 06/23/06, Approval Pending Modification to Update #4 (Protocol Version 05/17/06)
- Protocol Version 06/23/06
- Informed Consent Form for Protocol Version 06/23/06

COG AOST0331

Amendment Review: CIRB Acknowledgement of AOST0331 Worksheet Post Definitive Surgery Treatment Assignment form

Documentation posted:

- 07/14/06, AOST0331 Worksheet Post Definitive Surgery Treatment Assignment form
- 07/17/06, CIRB Acknowledgement of AOST0331 Worksheet Post Definitive Surgery Treatment Assignment form

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.