



NCI Central IRB Study Activity Update November 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@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 RB 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

ECOG E5103

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 10/13/06
- Protocol Version Date 06/13/06
- Informed Consent Form for Protocol Version Date 10/13/06
- Informed Consent Form for Protocol Version Date 06/13/06
- Summary of CIRB Application Revisions (Protocol Version Date 10/13/06)
- CIRB Application (Protocol Version Date 10/13/06)
- CIRB Application (Protocol Version Date 06/13/06)
- 12/27/06: CTEP Approval Letter (Protocol Version 10/13/06)
- 11/14/06: CTEP Review Letter
- 11/08/06: CIRB Final Approval (Protocol Version 10/13/06)
- 10/13/06: Group Response Letter
- 09/08/06: CIRB Revised Initial Review Approval Pending Modification (Protocol Version 06/13/06)
- 09/07/06: CIRB Revised Initial Review Approval Pending Modification (Protocol Version 06/13/06)
- 08/29/06: CIRB Initial Review Approval Pending Modification (Protocol Version 06/13/06)
- 07/17/06: CTEP Approval on Hold Letter (Protocol Version 06/13/06)
- 06/13/06: Group Response Letter
- 08/21/06: Minutes: Initial Review

Pediatric CIRB Studies

COG – AGCT0521

Initial Review 2006 Approval

Documents Posted:

- Protocol Version Date 01/25/07
- Protocol Version Date 01/25/07 - Highlighted Version
- Protocol Version Date 10/21/06
- Protocol Version Date 10/21/06 - Highlighted Version



- CIRB Application (Protocol Version Date 01/25/07)
- CIRB Application (Protocol Version Date 10/21/06)
- 03/06/07: CIRB Final Approval (Protocol Version Date 01/25/07)
- 01/25/07: Group Response Letter
- 12/18/06: CIRB Approval Pending Modification to Initial Review (Protocol Version Date 12/21/06)
- 10/27/06: CTEP Approval on Hold Letter
- 10/21/06: Group Response Letter

COG – ANBL0532

Initial Review 2007 Approval
Documents Posted:

- Protocol Version Date 05/29/07
- Protocol Version Date 05/29/07 - Highlighted Version
- Protocol Version Date 01/20/07
- Protocol Version Date 01/20/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 05/29/07 - Induction Therapy
- Informed Consent Form for Protocol Version Date 05/29/07 - Phases of Therapy for High Risk Neuroblastoma
- CIRB Application (Protocol Version Date 05/29/07)
- CIRB Application (Protocol Version Date 01/20/07)
- 07/05/07: CIRB Final Approval (Protocol Version Date 05/29/07)
- 05/29/07: CIRB Approval Pending Modification of the Group Response (Protocol Version Date 01/20/07)
- 04/03/07: CIRB Approval Pending Modification of the Group Response (Protocol Version Date 01/20/07)
- 01/18/07: Consensus Review Group Response Letter
- 11/22/06: Consensus Review

Other Activities Posted:

CALGB-10201

Amendment Review (AR): October 2007 Approval
Documents Posted:

- 06/15/07: Change Memo
- 10/09/07: CIRB Approval to Update #4 (Protocol Version Date 05/02/07)
- Protocol Version Date 05/02/07 Includes Update #4



CALGB-80303

Amendment Review (AR): September 2007 Approval

Documents Posted:

- 10/15/07: Protocol Revisions Update
- 08/31/07: Consensus Review
- 10/02/07: CIRB Update #9 Approval (Protocol Version 08/17/07)
- Protocol Version Date 08/17/07 (Includes Update #9)

COG – AALL0434

Amendment Review (AR): Amendment #1

Documents Posted:

- CIRB Application (Protocol Version Date 08/03/07)
- 10/08/07: CIRB Approval (Protocol Version 08/03/07)
- 08/28/07: Follow-Up Letter
- 08/03/07: Letter from the Group
- Protocol Version Date 08/03/07
- Protocol Version Date 08/03/07 - Highlighted Changes
- Informed Consent Form Protocol Version 08/03/07: Part I - Induction Therapy
- Informed Consent Form Protocol Version 08/03/07: Part II - Low Risk
- Informed Consent Form Protocol Version 08/03/07: Part II - Intermediate Risk
- Informed Consent Form Protocol Version 08/03/07: Part II - High Risk
- Informed Consent for Protocol Version 08/03/07: Optional Pharmacokinetic
- Informed Consent for Protocol Version 08/03/07: Part II - Induction Failure
- 09/27/07: Primary Reviewer 1 Comments
- 09/27/07: Amendment Review

COG – ADVL0524

Amendment Review (AR): CIRB Acknowledgement of Study Closure

Documents Posted:

- 11/06/07: Acknowledgement of Closure of Study ADVL0524
- 11/05/07: Memo re Closure of Study ADVL0524

COG – AGCT0521

Amendment Review (AR): Amendment #1

Documents Posted:

- CIRB Application (Protocol Version Date 08/28/07)
- 09/18/07: CIRB Approval to Amendment #1 (Protocol Version Date 08/28/07)



- 08/28/07: Change Memo
- Protocol Version Date 08/28/07
- Protocol Version Date 08/28/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 08/28/07

Continuing Review (CR): October 2007

- CIRB Continuing Review Application (Protocol Version Date 08/28/07)
- 10/16/07: CIRB Approval to Continuing Review October 2007 (Protocol Version Date 08/28/07)
- 08/28/07: Change Letter

COG – ANBL00P3

Continuing Review (CR): October 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/31/07)
- 10/30/07: CIRB Approval to Continuing Review October 2007 (Protocol Version Date 01/31/07)
- Protocol Version Date 01/31/07
- Protocol Version Date 01/31/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 01/31/07: High Risk
- Informed Consent Form for Protocol Version Date 01/31/07: Low Risk

COG-ARST0332

Continuing Review (CR): October 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/22/06)
- 10/30/07: CIRB Approval to Continuing Review October 2007 (Protocol Version Date 08/22/06)
- Protocol Version Date 08/22/06
- Informed Consent Form for Protocol Version Date 08/22/06

ECOG-E1Y03

Continuing Review (CR): November 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 11/15/06)
- 11/08/08: CIRB Continuing Review Approval November 2007 (Protocol Version 11/15/06)
- 11/06/07: Group Letter to Disregard Termination Request
- Protocol Version 11/15/06 [per CR Nov 2007]
- Informed consent for Protocol Version 11/15/06



ECOG-E1900

Amendment Review (AR): October 2007 Approval
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 09/06/07)
- 10/23/07: CIRB Approval Letter
- Protocol Version Date 09/06/07
- Informed Consent form for Protocol Version 09/06/07

ECOG-E5103

Amendment Review (AR): September 2007 Approval
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version 08/17/07)
- 09/25/07: CIRB Addendum #1 Approval September 2007 (Protocol Version 08/17/07)
- 08/20/07: CTEP-PIO Letter
- 08/17/07: Group Revision Letter
- Protocol Version Date 08/17/07 (Includes Addendum #1)
- Informed Consent Form for Protocol Version 08/17/07
- 09/17/07: NCI CIRB Minutes

ECOG-E5103

Continuing Review (CR): May 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 10/13/06)
- 05/25/07: CIRB Continuing Review Approval May 2007 (Protocol Version 10/13/06)
- Protocol Version 10/13/06
- Informed Consent Form for Protocol Version Date 10/13/06 [per May 2007 CR]
- Report of Studies November 2006

SWOG-S0205

Continuing Review (CR): October 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/21/07)
- 10/31/07: CIRB Continuing Review Approval Letter (Protocol Version 02/21/07)
- Protocol Version Date 02/21/07
- Report of Studies



SWOG-S0232

Continuing Review (CR): October 2007 Approval

Documents Posted:

- CIRB Continuing Review Application
- 11/01/07: CIRB Continuing Review Approval October 2007 (Protocol Version 06/01/07)
- Protocol Version Date 06/01/07
- 10/4-7/07: Report of Studies
- 05/09/07: DSMC Meeting Minutes
- Adverse Event Report
- Safety Reports

Corrections to Previous Study Activity Updates

ECOG-PACCT-1

Continuing Review (CR): September 2007 Approval

Documents Posted:

- Informed Consent for Protocol Version Date 07/16/07 (per Sep 07 Cr)

Correction:

Schema added to last page of consent and pagination was corrected within consent document.

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.