



NCI Central IRB Study Activity Update

June 15, 2008

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.

Adult CIRB Studies

CALGB-40503

Initial Review 2008 Approval
Documents Posted:

- Protocol Version Date 02/14/08
- Protocol Version Date 10/08/07
- Protocol Version Date 08/15/07
- Appendix C: Specimen Banking Policies & Guide to Access to CALGB Specimens
- Informed Consent Document for Protocol Version Date 02/14/08
- CIRB Application (Protocol Version Date 02/14/08)
- Summary of CIRB Application Revisions (Protocol Version Date 02/14/08)
- CIRB Application (Protocol Version Date 10/08/07)
- CIRB Application (Protocol Version Date 08/15/07)
- 05/16/08: CIRB Acknowledgement of Activation (Protocol Version Date 02/14/08)
- 05/15/08: CALGB Activation Memo
- 03/10/08: CIRB Approval of Activation Amendment (Protocol Version Date 02/14/08)
- 02/14/08: CALGB Activation Amendment Memo
- 11/29/07: CIRB Group Response Approval Letter (Protocol Version Date 10/08/07)
- 10/26/07: CALGB Response to CIRB Stipulations
- 10/08/07: CIRB Approval Pending Modification Letter (Protocol Version Date 08/15/07)
- 09/17/07: Minutes: Initial Review



Pediatric CIRB Studies

COG-ACNS0621

Initial Review 2007 Approval
Documents Posted:

- Protocol Version Date 03/21/08
- Protocol Version Date 03/21/08 - Highlighted Changes
- Protocol Version Date 11/01/07
- Protocol Version Date 11/01/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 03/21/08
- CIRB Application Protocol Version Date 03/21/08
- CIRB Application Protocol Version Date 11/01/07
- 12/13/07: Primary Reviewer 1 Comments
- 12/13/07: Primary Reviewer 2 Comments
- 12/13/07: Primary Reviewer 3 Comments
- 04/11/08: CIRB Approval Letter (Protocol Version Date 03/21/08)
- 03/24/08: COG Response to Approval Pending Modification (Protocol Version Date 11/01/07)
- 01/15/08: CIRB Approval Pending Modification (Protocol Version Date 11/01/07)
- 12/13/07: Minutes - Initial Review

COG-AEPI05N1

Initial Review 2007 Approval
Documents Posted:

- Protocol Version Date 01/25/08
- Protocol Version Date 01/25/08 - Highlighted Changes
- Protocol Version Date 11/26/07
- Protocol Version Date 11/26/07 - Highlighted Changes
- Protocol Version Date 07/18/07
- CIRB Application (Protocol Version Date 01/25/08)
- CIRB Application (Protocol Version Date 11/26/07)
- CIRB Application (Protocol Version Date 07/18/07)
- 12/13/07: Primary Reviewer 1 - Comments
- 10/11/07: Primary Reviewer 1 - Comments
- 10/11/07: Primary Reviewer 2 - Comments
- 10/11/07: Primary Reviewer 3 - Comments
- 02/07/08: CIRB Final Approval Letter (Protocol Version Date 01/25/08)
- 01/24/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 01/25/08)
- 01/15/08: CIRB Approval Pending Modification (Protocol Version Date 11/26/07)



- 11/16/07: COG Response to Tabled Action Letter (Protocol Version Date 11/26/07)
- 10/30/07: CIRB Tabled Letter (Protocol Version Date 07/18/07)
- 12/13/07: Minutes - Group Response to Tabled Initial Review
- 10/11/07: Minutes - Initial Review

Other Activity Posted:

ACOSOG-Z1041

Amendment Review (AR) Amendment #2 Approval April 2008

Documents Posted:

- 03/17/08: Change Memo (Protocol Version Date 03/17/08)
- CIRB Application (Protocol Version Date 03/17/08)
- Summary of CIRB Application Revisions
- 06/05/08: CIRB Acknowledgement of Activation (Protocol Version Date 03/17/08)
- 04/09/08: CIRB Amendment #2 Approval Letter (Protocol Version Date 03/17/08)
- Protocol Version Date 03/17/08
- Protocol Version Date 03/17/08 (Highlighted)
- Informed Consent Document for Protocol Version Date 03/17/08: Step 1
- Informed Consent Document for Protocol Version Date 03/17/08: Step 2

CALGB-90203

Continuing Review (CR) Approval June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/12/08)
- 06/10/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/08)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 02/12/08
- Informed Consent Document for Protocol Version Date 02/12/08 [Per June 08 CR]
- October 2007: Study Summary



CALGB-SWOG-C80405

****Suspension of Accrual - Effective Friday June 6, 2008 at 5pm EST (Patients consented thru June 6, 2008 may enroll until June 16, 2008)****

Documents Posted:

- 06/11/08: CIRB Approval of Patient Information Letter (Protocol Version Date 09/14/07)
- 06/10/08: CIRB Acknowledgement of Receipt of Suspension (Protocol Version Date 09/14/07)
- 06/06/08: Group Action Letter
- 06/06/08: Group Investigator Letter
- 06/06/08: Group Participant Letter

COG-AALL0434

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

COG-AALL06N1

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

COG-AALL0631

Continuing Review (CR) Continuing Review May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/02/07)
- 02/06/08: CIRB Continuing Review Approval Letter (Protocol Version Date 11/02/07)
- 05/30/08: COG Response to Approval Pending Modification (Protocol Version Date 11/02/07)
- 05/28/08: CIRB Approval Pending Modification Letter (Protocol Version Date 11/02/07)



- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/02/07
- Informed Consent Document for Protocol Version Date 11/02/07 - Part 1 non-Phase 1
- Informed Consent Document for Protocol Version Date 11/02/07 - Part 2
- Informed Consent Document for Protocol Version Date 11/02/07 - Part 1 Phase 1 Inst

COG-ACCRN07

Initial Review 2007

Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes – Group Response to Initial Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

COG-AEPI05N1

Amendment Review (AR) Amendment #AA1

Documents Posted:

- CIRB Application (Protocol Version Date 04/24/08)
- 05/13/08: CIRB Approval Letter (Protocol Version Date 04/24/08)
- 04/24/08: Change Memo (Protocol Version Date 04/24/08)
- Protocol Version Date 04/24/08
- Protocol Version Date 04/24/08 - Highlighted Changes
- Inform Consent Document for Protocol Version Date 04/24/08 - CASE SUBJECTS
- Inform Consent Document for Protocol Version Date 04/24/08 - CONTROL SUBJECTS

COG-AHOD0431

Continuing Review (CR) Continuing Review August 2007

Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.



COG-ANBL00B1

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/06/07)
- 06/02/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/07)
- 05/28/08: COG Response to Approval Pending Modification (Protocol Version Date 08/06/07)
- 05/28/08: CIRB Approval Pending Modification Letter (Protocol Version Date 08/06/07)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/06/07
- Informed Consent Document for Protocol Version Date 08/06/07
- 10/01/07: Study Progress Report

COG-ANHL04B1

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/03/07)
- 05/28/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/03/07)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/03/07
- Informed Consent Document for Protocol Version Date 08/03/07

COG-AOST0331

Continuing Review (CR) Continuing Review May 2008

Documents Posted:

- CIRB Group Response Continuing Review Application (Protocol Version Date 09/21/07)
- CIRB Continuing Review Application (Protocol Version Date 09/21/07)
- 06/09/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/21/07)
- 05/13/08: CIRB Tabled Letter (Protocol Version Date 09/21/07)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/21/07
- Informed Consent for Protocol Version Date 09/21/07: Part 1: Induction Therapy
- Informed Consent Document for Protocol Version Date 09/21/07: Part 2: Good Response



- Informed Consent Document for Protocol Version Date 09/21/07: Part 2: Poor Response
- 10/25/07: DSMC Report

COG-AREN0321

Continuing Review (CR) Continuing Review August 2007
Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

COG-ARET0332

Continuing Review (CR) Continuing Review August 2007
Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes - Continuing Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

COG-AREN0532

Amendment Review (AR) Amendment Review August 2007
Documents Posted:

- 08/09/07: Primary Reviewer 1 Comments
- 08/09/07: Minutes - Amendment Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.

COG-ASCT0631

Amendment Review (AR) Amendment Review August 2007
Documents Posted:

- 08/23/07: Primary Reviewer 1 Comments
- 08/23/07: Minutes - Amendment Review

Additional documents associated with this action have been previously posted to the Study Activity Update and are available on the website.



COG-D9902

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/02/07)
- 06/02/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/02/07)
- 05/30/08: COG Response to Approval Pending Modification (Protocol Version Date 04/02/07)
- 05/28/08: CIRB Approval Pending Modification Letter (Protocol Version Date 04/02/07)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 04/02/07
- Informed Consent Document for Protocol Version Date 04/02/07

ECOG-E1900

Amendment Review (AR) Addendum #9 Approval March 2008

Documents Posted:

- 03/12/08: Change Memo (Protocol Version Date 02/19/08)
- CIRB Application (Protocol Version Date 02/19/08)
- Summary of CIRB Application Revisions (Protocol Version Date 02/19/08)
- 04/02/08: CIRB Addendum #9 Approval Letter (Protocol Version Date 03/12/08)
- 03/03/08: CIRB Approval Pending Modification (Protocol Version Date 02/19/08)
- Protocol Version Date 03/12/08
- Protocol Version Date 02/19/08
- Informed Consent Document for Protocol Version Date 03/12/08 [Per Add 9]
- 02/22/08: Primary Reviewer 1 Comments
- 02/22/08: Minutes: Addendum #9 Review

ECOG-E2100

Continuing Review (CR) Approval June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/30/07)
- 06/10/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/30/07)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 05/30/07
- DMC Recommendations - Meetings 03/09/05 & 04/06/05
- NE Journal of Medicine Abstract



ECOG-E3805

Continuing Review (CR) Approval June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/02/07)
- 06/10/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/02/07)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 01/02/07
- Informed Consent Document for Protocol Version Date 01/02/07 [Per June 08 CR]
- Report of Studies Dated November 2007
- 09/24/07: DMC Recommendations

ECOG-E3999

Continuing Review (CR) Approval June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/01/05)
- 06/10/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/01/05)
- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 06/01/05
- Study Summary
- 04/18/06: DMC Recommendations

ECOG-E4402

Continuing Review (CR) Approval June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/24/07)
- 06/10/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/24/07)
- 05/09/08: Continuing Review Reminder Notice
- Protocol Version Date 08/24/07
- Informed Consent Document for Protocol Version Date 08/24/07 [Per June 08 CR]
- 09/24/07: DMC Recommendations
- Pharmacokinetic Analysis
- Report of Studies Dated November 2007



NCCTG-N0147

****Suspension of Accrual - Effective Friday June 6, 2008 at 5pm EST (Patients consented thru June 6, 2008 may enroll until June 13, 2008)****

Documents Posted:

- 06/11/08: CIRB Approval of Patient Information Letter (Protocol Version Date 01/31/08)
- 06/10/08: CIRB Acknowledgement of Suspension (Protocol Version Date 01/31/08)
- 06/06/08: Group Notification of Action Letter
- 06/06/08: Group Status Change Notice
- 06/06/08: Group Investigator Letter

NCIC CTG-MA.27B

****Study Closed to Accrual Effective as of 6:00 pm EST on Friday May 30, 2008****

Documents Posted:

- 06/04/08: CIRB Acknowledgement of Receipt-Closure to Accrual (Protocol Version Date 05/22/07)
- 05/09/08: Notification of Closure to Accrual

NCIC CTG-PR.11

Amendment Review (AR) Amendment 1 Approval June 2008

Documents Posted:

- 04/08/08: Change Memo (Protocol Version Date 04/07/08)
- CIRB Application (Protocol Version Date 04/07/08)
- Summary of CIRB Application Revisions
- 06/06/08: CIRB Acknowledgement of Activation (Protocol Version Date 04/07/08)
- 06/05/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 04/07/08)
- Protocol Version Date 04/07/08
- Informed Consent Document for Protocol Version Date 04/07/08 [Per Am 1]

RTOG-0534

Continuing Review (CR) Approval June 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/03/07)
- 06/10/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/03/07)



- 04/07/08: Continuing Review Reminder Notice
- Protocol Version Date 10/03/07
- Informed Consent Document for Protocol Version Date 10/03/07 [Per June 08 CR]
- January 2008: Study Summary
- 01/11/08: DMC Minutes

SWOG-S0106

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/28/08)
- 06/09/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/08)
- 03/05/08: Continuing Review Reminder Notice
- Protocol Version Date 03/28/08
- Informed Consent Document for Protocol Version Date 03/28/08 [Per May 08 CR]
- 05/19/08: Primary Reviewer 1 Comments
- May 2008: Study Summary
- 10/11/07: DSMC Minutes
- 05/09/07: DSMC Minutes

SWOG-S0307

Amendment Review (AR) Amendment #2 Approval May 2008

Documents Posted:

- CIRB Application (Protocol Version Date 03/11/08)
- Summary of CIRB Application Revisions
- 06/04/08: CIRB Acknowledgement of Activation (Protocol Version Date 03/11/08)
- 05/07/08: CIRB Amendment #2 Approval Letter (Protocol Version Date 03/11/08)
- Protocol Version Date 03/11/08
- Informed Consent Document for Protocol Version Date 03/11/08 [per Am 2]
- 04/21/08: Minutes - Amendment #2 Review

SWOG-S0309

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/12/07)
- 06/04/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/07)
- 03/05/08: Continuing Review Reminder Notice



- Protocol Version Date 02/12/07
- 05/19/08: Primary Reviewer 1 Comments
- October 2007: Study Summary

SWOG-S0600

****Suspension of Accrual - Effective Friday June 6, 2008 at 5pm EST****

Documents Posted:

- 06/11/08: CIRB Approval of Patient Information Letter (Protocol Version Date 04/10/08)
- 06/10/08: CIRB Acknowledgement of Notification of Suspension (Protocol Version Date 04/10/08)
- 06/06/08: Action Letter - CETUXIMAB
- 06/06/08: Group Investigator Letter
- 06/06/08: Group Temporary Closure Letter

Corrections to Previous Study Activity Updates

SWOG-S0502

Amendment Review Amendment #1 Approval January 2008

Documents Posted:

Informed Consent Document for Protocol Version Date 11/26/07 (Per Am 1)

Correction:

Informed Consent Document replaced with correct version.

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.