



NCI Central IRB Study Activity Update

February 29, 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.

Pediatric CIRB Studies

COG – AEWS0521

Initial Review 2006 Approval
Documents Posted:

- Protocol Version Date 02/08/07
- Protocol Version Date 02/08/07 - Highlighted Version
- Protocol Version Date 12/12/06
- Protocol Version Date 12/12/06 - Highlighted Version
- Protocol Version Date 08/31/06
- Protocol Version Date 08/31/06 - Highlighted Version
- CIRB Application (Protocol Version Date 02/08/07)
- CIRB Application (Protocol Version Date 12/12/06)
- CIRB Application (Protocol Version Date 08/31/06)
- 01/11/07: Primary Reviewer 1 Comments
- 11/09/06: Primary Reviewer 1 Comments
- 11/09/06: Primary Reviewer 2 Comments
- 11/09/06: Primary Reviewer 3 Comments
- 11/09/06: Pharmacist Comments
- 02/20/07: CIRB Final Approval (Protocol Version Date 02/08/07)
- 02/08/07: Group Response Letter
- 02/01/07: CIRB Approval Pending Modification to Initial Review (Protocol Version Date 12/12/06)
- 12/12/06: Group Response Letter
- 11/21/06: CIRB Approval Pending Modification to Initial Review November 2006 (Protocol Version Date 08/31/06)
- 08/31/06: Group Response Letter
- 01/11/07: Minutes - Group Response to Initial Review
- 11/09/06: Minutes - Initial Review



Other Activities Posted:

CALGB-10201

Continuing Review (CR): January 2008 Approval
Documents Posted:

- 01/14/08: Primary Reviewer Comments
- 01/14/08: CIRB Meeting Minutes

CALGB-10501

Continuing Review (CR): February 2008 Approval
Documents Posted:

- CIRB Continuing Review Application
- 02/20/08: CIRB Continuing Review Approval February 2008 (Protocol Version 10/17/07)
- Protocol Version 10/17/07
- Informed Consent for Protocol Version 10/17/07 [per Feb 08 CR]

CALGB-40101

Amendment Review (AR): Update #8 (Protocol Version Date 11/08/07)
Documents Posted:

- CIRB Amendment Review Application (Protocol Version 11/08/07)
- Summary of CIRB Application Revisions (Protocol Version 11/08/07)
- 01/09/08: CIRB Amendment Review Approval December 2007 (Protocol Version 11/08/07)
- Protocol Version 11/08/07
- Informed Consent for Protocol Version 11/08/07 [per Up 8 Dec 07]
- 12/17/07: CIRB Meeting Minutes

CALGB-40302

Amendment Review (AR): Update #2 (Protocol Version Date 12/11/07)
Documents Posted:

- CIRB Amendment Review Application (Protocol Version 12/11/07)
- Summary of CIRB Application Revisions
- 01/22/08: CIRB Amendment Review Approval January 2008 (Protocol Version 12/11/07)
- 12/12/07: Group-CTEP Response Letter
- Study Summary
- Protocol Version 12/11/07
- Informed Consent for Protocol Version 12/11/07 [per Up 2 Jan 08]
- 01/13/08: Reviewer Comments
- 01/14/08: CIRB Meeting Minutes



CALGB-49907

Continuing Review (CR): February 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/31/07)
- 02/25/08: CIRB Continuing Review Approval February 2008 (Protocol Version 01/31/07)
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 01/31/07
- 02/22/08: Reviewer Comments
- 01/08/08: ASCO (HD Muss Document)
- Study Summary June 2007

CALGB-SWOG-C80405

Amendment Review (AR): Update #4 (Protocol Version Date 12/18/07)

Documents Posted:

- Summary of CIRB Application Revisions (Protocol Version 12/18/07)
- CIRB Review Application (Protocol Version 09/14/07)
- Summary of CIRB Application Revisions (Protocol Version 09/14/07)
- 01/08/08: CIRB Update 4 Approval January 2008 (Protocol Version 12/18/07)
- 12/18/07: Group Letter-CIRB
- 12/04/07: CIRB Approval Pending Modifications (Protocol Version 09/14/07)
- 09/20/07: CTEP Recommendation Letter
- 02/15/08: Study Summary
- 12/15/07: Study Summary
- Protocol Version 12/18/07
- Protocol Version 09/14/07
- Informed Consent for Protocol Version 12/18/07 [per Up#4]
- 11/08/07: CIRB Meeting Minutes

COG-AALL03B1

Amendment Review (AR): Amendment #5 (Protocol Version Date 01/24/08)

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/24/08)
- 02/11/08: CIRB Approval of Amendment #5 February 2008 (Protocol Version Date 01/24/08)
- 01/24/08: Change Letter
- Protocol Version Date 01/24/08
- Protocol Version Date 01/24/08 - Highlighted Version
- Informed Consent Form for Protocol Version 01/24/08 - Additional Bone Marrow



- Informed Consent Form for Protocol Version 01/24/08 - Study Entry & Shipment of Samples

COG-AALL0434

Acknowledgement Memo re Enrollment Suspension for Down Syndrome Patients Documents Posted:

- 02/20/08: CIRB Acknowledgement of Enrollment Suspension for Down Syndrome Patients
- 02/20/08: Memo of Enrollment Suspension for Down Syndrome Patients

COG-AAML0431

Continuing Review (CR): February 2008 Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/07/07)
- 02/21/08: CIRB Approval to Continuing Review February 2008 (Protocol Version Date 02/07/07)
- 12/14/07: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/07/07
- Informed Consent Form for Protocol Version Date 02/07/07
- 10/16/07: DSMC Report
- Study Progress Report Dated 10/01/07

COG – AEWS0521

Amendment Review (AR): Activation Amendment (Protocol Version Date 01/31/08) Documents Posted:

- CIRB Application (Protocol Version Date 01/31/08)
- CIRB Application (Protocol Version Date 12/05/07)
- CIRB Application (Protocol Version Date 05/04/07)
- 02/15/08: CIRB Approval of Amendment February 2008 (Protocol Version Date 01/31/08)
- 01/31/08: Group Response Letter
- 01/21/08: CIRB Approval Pending Modification of Amendment January 2008 (Protocol Version Date 01/31/08)
- 12/05/07: Group Revision Letter
- 07/05/07: CIRB Approval of Amendment July 2007 (Protocol Version Date 05/04/07)
- 05/04/07: Group Change Letter
- Protocol Version Date 01/31/08
- Protocol Version Date 01/31/08 - Highlighted Version
- Protocol Version Date 12/05/07
- Protocol Version Date 12/05/07 - Highlighted Version



- Protocol Version Date 05/04/07
- Informed Consent Form for Protocol Version Date 01/31/08 – Part I - Feasibility
- Informed Consent Form for Protocol Version Date 01/31/08 - Part II - Randomized Study

Continuing Review September 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/04/07)
- 09/18/07: CIRB Approval to Continuing Review September 2007 (Protocol Version Date 05/04/07)
- 07/10/07: CIRB Continuing Review Reminder Notice

COG-AHOD04B1

Continuing Review (CR): February 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/30/07)
- 02/21/08: CIRB Approval to Continuing Review February 2008 (Protocol Version Date 04/30/07)
- 12/14/07: CIRB Continuing Review Reminder Notice
- Protocol Version Date 04/30/07
- Informed Consent Form for Protocol Version Date 04/30/07
- Study Progress Report Dated 10/01/07

ECOG-E1900

Continuing Review (CR) February 2008 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/06/07)
- 02/15/08: CIRB Continuing Review Approval February 2008 (Protocol Version 09/06/07)
- 12/11/07: CIRB Continuing Review Notice
- Protocol Version 09/06/07
- Informed Consent for Protocol Version 09/06/07 [per Feb 08 CR]
- 01/31/08: Primary Reviewer Comments
- 02/01/08: CIRB Meeting Minutes
- 09/24/07: DMC Recommendations

ECOG-E3201

Continuing Review (CR) January 2008 Approval
Documents Posted:

- 01/14/08: CIRB Meeting Minutes



ECOG-E5103

Continuing Review (CR) February 2008 Approval
Documents Posted:

- CIRB Continuing Review Application Protocol Version 12/26/07
- 02/25/08: CIRB Continuing Review Approval February 2008 (Protocol Version 12/26/07)
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 12/26/07
- Informed Consent for Protocol Version 12/26/07 [per Feb 08 CR]
- 02/22/08: Primary Reviewer Comments
- Study Summary November 2007
- New England Journal of Medicine Article

ECOG-E5202

Continuing Review (CR) February 2008 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/07/07)
- 02/19/08: CIRB Continuing Review Approval February 2008 (Protocol Version 03/07/07)
- 11/26/07: CIRB Continuing Review Notice
- Protocol Version 03/07/07
- Informed Consent for Protocol Version 03/07/07 [per Feb 08 CR]
- 01/31/08: Primary Reviewer Comments
- 02/01/08: CIRB Meeting Minutes
- November 2007-Study Summary
- 09/24/07: DMC Minutes

NCCTG-N0574

Continuing Review (CR) January 2008 Approval
Documents Posted:

- 01/14/08: Primary Reviewer Comments
- 01/14/08: CIRB Meeting Minutes

NSABP-B-33

Continuing Review (CR) February 2008 Approval
Documents Posted:

- 02/01/08: CIRB Meeting Minutes



NSABP-B-39/RTOG-0413

Continuing Review (CR) February 2008 Approval

Documents Posted:

- 02/01/08: CIRB Meeting Minutes

NSABP-C-08

Amendment Review (AR): Amendment 7 (Protocol Version 10/25/07)

Documents Posted:

- Summary of Changes Protocol Version 10/25/07
- 01/07/08: CIRB Amendment Review Approval November 2007 (Protocol Version 10/25/07)
- 10/05/07: Group-CTEP Cover Letter
- Protocol Version 10/25/07

Amendment Review (AR): Amendment 6 (Protocol Version 08/02/07)

Documents Posted:

- Summary of Changes Protocol Version 08/02/07
- Summary of Changes Protocol Version 03/27/07
- 10/05/07: CIRB Amendment Review Approval September 2007 (Protocol Version 08/02/07)
- 08/24/07: Group-CIRB Response Letter
- 06/19/07: CIRB Approval Pending Modifications (Protocol Version 03/27/07)
- 04/20/07: Group-CTEP Cover Letter
- Protocol Version 08/02/07
- Protocol Version 03/27/07
- 09/17/07: CIRB Meeting Minutes
- 05/21/07: CIRB Meeting Minutes

NSABP-R-04

Continuing Review (CR) February 2008 Approval

Documents Posted:

- 02/01/08: CIRB Meeting Minutes

SWOG-S0226

Continuing Review (CR) January 2008 Approval

Documents Posted:

- 01/03/08: Primary Reviewer Comments
- 01/04/08: CIRB Meeting Minutes



SWOG-S0334

Amendment Review (AR): Closure of Study
Documents Posted:

- 01/28/08: CIRB Closure of Study

SWOG-S0500

Continuing Review (CR) January 2008 Approval
Documents Posted:

- 01/11/08: Primary Reviewer Comments
- 01/14/08: CIRB Meeting Minutes

SWOG-S0518

Continuing Review (CR) February 2008 Approval
Documents Posted:

- 02/01/08: CIRB Meeting Minutes

Serious Adverse Events

Study: NSABP C-08
SAE Posted: 234306, 235298, 236761, 242575, Oxaliplatin Investigator Notification (7-23-07)

Study: ECOG 1A05
SAE Posted: 163-C5013-07071689(2)

Study: CALGB 100104
SAE Posted: 163-C5013-07071689(2)

Study: RTOG 0320
SAE Posted: 2007SP007552(4), 2007SP007552(5), 2007SP014751(2)

Study: RTOG 0525
SAE Posted: 2007SP007552(4), 2007SP007552(5), 2007SP014751(2)

Study: CALGB 80203
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: ECOG 3200
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: ECOG 3201
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)



Study: ECOG 5202
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: ECOG 5204
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: ECOG 6201
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: NCCTG N0147
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: NSABP C-09
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: NSABP R-04
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Study: SWOG 0303
SAE Posted: Oxaliplatin Investigator Notification (7-23-07)

Corrections to Previous Study Activity Updates

ECOG-E5103

Amendment Review Amendment 2-Local Update 1 Approval November 2007
Documents Posted:

Summary of CIRB Application Revisions

Correction: Version date corrected in Summary of CIRB Application Revisions.

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.