



NCI Central IRB Study Activity Update November 30, 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. ******



Activity Posted:

CALGB-30102

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/07/03)
- 11/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/07/03)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 08/07/03
- June 2005 - Study Summary

CALGB-49907

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/31/07)
- 11/20/08: CIRB Continuing Review Approval Letter (Protocol Version Date 01/31/07)
- 10/01/08: Continuing Review Reminder Notice
- Protocol Version Date 01/31/07
- 11/12/08: Primary Reviewer 1 Comments
- Abstract 6542
- June 2007 - Study Summary

CALGB-SWOG-C80405

REACTIVATION OF CALGB/SWOG 80405

Documents Posted:

- 11/11/08: CIRB Acknowledgement of Receipt-Reactivation of Study
- 11/07/08: Notification of Re-Activation of Study

CALGB-SWOG-C80405

****Effective November 17, 2008, CALGB/SWOG 80405, has been temporarily closed to patient accrual.***

Documents Posted:

- CALGB Notification of Temporary Suspension of Accrual

COG-AALL0331

Amendment Review (AR): Amendment #3 (Protocol Version Date 10/10/08)

Documents Posted:



- CIRB Application (Protocol Version Date 10/10/08)
- 11/12/08: CIRB Approval Letter (Protocol Version Date 10/10/08)
- 10/10/08: COG Change Memo (Protocol Version Date 10/10/08)
- Protocol Version Date 10/10/08
- Protocol Version Date 10/10/08 Highlighted Changes
- Informed Consent Document for Protocol Version Date 10/10/08 - Induction Therapy
- Informed Consent Document for Protocol Version Date 10/10/08 - Standard Risk Low
- Informed Consent Document for Protocol Version Date 10/10/08 - Standard Risk Average
- Informed Consent Document for Protocol Version Date 10/10/08 - Standard Risk High
- Informed Consent Document for Protocol Version Date 10/10/08 - Treatment Changes

COG-AALL0631

****Temporarily Closed to Accrual by COG - Effective November 19, 2008****

Amendment Review (AR): CIRB Acknowledgement of Temporary Closure to Accrual

Documents Posted:

- 11/21/08: CIRB Acknowledgement of Temporary Suspension of Accrual
- 11/19/08: COG Temporary Suspension of Enrollment

COG-AALL0631

Amendment Review (AR): Clarification of definition of lestaurtinib-related DLTs on AALL0631

Documents Posted:

- 11/24/08: CIRB Acknowledgement of Clarification of the Definition of Lestaurtinib-Related Dose Limiting Toxicities
- 11/14/08: COG Clarification of definition of lestaurtinib-related DLTs

COG-AALL07P4

Amendment Review (AR): CIRB Acknowledgement Memo re: Notification of Discrepancy Found in Informed Consent Document

Documents Posted:

- 11/18/08: CIRB Acknowledgement of Discrepancy
- 11/14/08: COG Memo -Typographical Error in the Sample Informed Consent Document



COG-ACCL05C1

****Temporarily Closed to Accrual by COG - Effective November 11, 2008****

Amendment Review (AR): CIRB Acknowledgement of Temporary Closure to Accrual

Documents Posted:

- 11/21/08: CIRB Acknowledgement of Receipt-Temporary Closure to Accrual
- 10/31/08: COG Temporary Closure Memo

COG-ACNS0332

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/15/07)
- 11/20/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/15/07)
- 11/12/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/15/07)
- 11/06/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/15/07)
- 09/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/15/07
- Protocol Version Date 02/15/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 02/15/07
- 08/25/08: Study Progress Report
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

COG-AREN03B2

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/23/08)
- 11/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/23/08)
- 11/12/08: COG Response to CIRB Approval Pending Modification (Protocol Version Date 05/23/08)
- 11/07/08: CIRB Approval Pending Modification (Protocol Version Date 05/23/08)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/23/08
- Informed Consent Document for Protocol Version Date 05/23/08 [per Oct08 CR]



- 04/11/08: DSMC Information
- Spring 2008 - Study Summary

ECOG-E1302

Closed to Accrual-Effective November 13, 2008

Documents Posted:

- 11/17/08: CIRB Acknowledgement of Receipt-Closed to Accrual
- 11/13/08: ECOG E1302 Protocol Notice-Closed to Accrual

ECOG-E3201

Continuing Review (CR) November 2008 Approval (Protocol Version Date 06/26/08)

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/26/08)
- 11/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 06/26/08
- June 2006 - Study Summary
- March-April, 2005 DMC Meetings

ECOG-E5202

Continuing Review (CR) November 2008 Approval (Protocol Version Date 05/14/08)

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/29/08)
- 11/24/08: CIRB Corrected Continuing Review Approval Letter (Protocol Version Date 05/14/08)
- 11/24/08: CIRB Correction to Approval Letter dated 11/17/08
- 11/17/08: CIRB Continuing Review Approval Letter (Protocol Version Date 07/29/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 05/14/08
- Informed Consent Document for Protocol Version Date 05/14/08 [Nov08 CR]
- 11/07/08: Primary Reviewer 1 Comments
- November 2008 - Study Summary
- 05/09/08: DMC Recommendations

ECOG-E5204

Protocol Notice on Reconsenting Patients dated 10/29/08

Documents Posted:



- 11/13/08: CIRB Acknowledgement of Receipt-Protocol Notice on Reconsenting Patients
- 10/29/08: ECOG Protocol Notice on Reconsenting Patients

NSABP-B-33

Continuing Review (CR) November 2008 Approval (Protocol Version Date 03/26/07)

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/26/07)
- 11/19/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
- 10/20/08: NSABP Continuing Review Cover Memo
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 03/26/07
- 11/07/08: Primary Reviewer 1 Comments
- 04/20/08: Journal of Clinical Oncology Abstract
- Study Summary

NSABP-B-39/RTOG-0413

Continuing Review (CR) November 2008 Approval (Protocol Version Date 03/13/07)

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/13/07)
- 11/19/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/13/07)
- 10/20/08: NSABP Continuing Review Cover Memo
- 09/05/08: Continuing Review Reminder Notice
- 03/19/07: NSABP Amendment 3 Cover Memo
- Protocol Version Date 03/13/07
- Informed Consent Document (Notes for Local Institutions) for Protocol Version Date 03/13/07 [Nov08 CR]
- Informed Consent Document for Protocol Version Date 03/13/07 [Nov08 CR]
- 11/07/08: Primary Reviewer 1 Comments
- 10/20/08: PubMed Central Publication
- 04/25/08: DMC Minutes
- Study Summary

NSABP-R-04

Continuing Review (CR) November 2008 Approval (Protocol Version Date 09/04/08)

Documents Posted:



- CIRB Continuing Review Application (Protocol Version Date 09/04/2008)
- 11/17/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/04/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 09/04/2008
- Informed Consent Document for Protocol Version Date 09/04/08 [Nov08 CR]
- Informed Consent Document-Tissue for Protocol Version Date 09/04/2008 [Nov08 CR]
- Informed Consent Document-Tissue (Notes for Local institutions) for Protocol Version Date 09/04/2008 [Nov08 CR]
- 11/07/08: Primary Reviewer 1 Comments
- 04/25/08: DMC Minutes
- Study Summary

RTOG-0129

Amendment Review (AR) August 2008 Approval (Protocol Version Date 08/06/08)

Note: This Action was inadvertently not posted when approved in August of 2008.

Documents Posted:

- Change Memo-Amendment 6 (Protocol Version Date 08/06/08)
- 08/28/08: CIRB Acknowledgement of Receipt-Posting of Amendment 6 (Protocol Version Date 08/06/08)
- 08/25/08: CIRB Amendment 6 Approval Letter (Protocol Version Date 08/06/08)
- 08/06/08: RTOG Cover Letter-Amendment 6 (Protocol Version Date 08/06/08)
- Protocol Version Date 08/06/08
- Protocol Version Date 08/06/08 (Highlighted)
- Informed Consent Document for Protocol Version Date 08/08/08 [Am6]

RTOG-0617

Amendment Review (AR) Amendment 2 (Protocol Version Date 08/29/08)

Documents Posted:

- CIRB Revised Review Application (Protocol version Date 08/29/08)
- 11/25/08: CIRB Acknowledgement of Receipt-Revised CIRB Application (Protocol Version Date 08/29/08)

SWOG-S0518

Continuing Review (CR) November 2008 Approval (Protocol Version Date 06/19/08)

Documents Posted:



- CIRB Continuing Review Application (Protocol Version Date 06/19/08)
- 11/17/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/19/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 06/19/08
- Informed Consent Document for Protocol Version Date 06/19/08 [Per Nov08 CR]
- Informed Consent Document for Protocol Version Date 06/19/08 [Notes for Local Institutions]
- 11/07/08: Primary Reviewer 1 Comments
- 05/09/08: DSMC Minutes
- Fall 2008 - Study Summary

SWOG-S0777

Continuing Review (CR) November 2008 Approval (Protocol Version Date 09/17/08)

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/17/08)
- 11/11/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/17/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 09/17/08
- Informed Consent Document for Protocol Version Date 09/17/08 [Per Nov08 CR]
- Informed Consent Document (Notes for Local Institution) for Protocol Version Date 09/17/08

Serious Adverse Events

**Study: CALGB 40502
SAE Posted: 1285866**

**Study: CALGB 40503
SAE Posted: 1285866**

**Study: CALGB 80303
SAE Posted: 1285866**

**Study: CALGB 90206
SAE Posted: 1285866**

**Study: CALGB 90401
SAE Posted: 1285866**



Study: CALGB SWOG C80405
SAE Posted: 1285866

Study: ECOG E1105
SAE Posted: 1285866

Study: ECOG E1305
SAE Posted: 1285866

Study: ECOG E1505
SAE Posted: 1285866

Study: ECOG E2100
SAE Posted: 1285866

Study: ECOG E4599
SAE Posted: 1285866

Study: ECOG E5103
SAE Posted: 1285866

Study: ECOG E5202
SAE Posted: 1285866

Study: ECOG E5204
SAE Posted: 1285866

Study: GOG 0213
SAE Posted: 1285866

Study: GOG 0218
SAE Posted: 1285866

Study: NSABP B-34
SAE Posted: 200824407 SU93 FU1, 2008266944 SU102, 200833071 SU100, 200833892 SU101

Study: NSABP B-38
SAE Posted: IE200809003408, MX200808002967 FU1

Study: NSABP B-40
SAE Posted: 1285866, 1506455, 1636469, 1820686, 1843518, 1859262, 232048 FU3, 232048 FU4, 263914 FU2, 265652 FU1, 265688, IE200809003408, MX200808002967 FU1



Study: NSABP C-08
SAE Posted: 1285866, 1506455, 1636469, 1820686, 1843518, 1859262, 232048 FU3, 232048 FU4, 257028 FU3, 263914 FU2, 265652 FU1, 265688

Study: RTOG 0436
SAE Posted: 08-02-14861, 08-02-15188

Study: RTOG 0522
SAE Posted: 08-02-14861, 08-02-15188

Study: SWOG S0502
SAE Posted: 1285866

Study: SWOG S0518
SAE Posted: 1285866

Study: SWOG S0600
SAE Posted: 1285866

Corrections to Previous Study Activity Updates

NCCTG-N0723

Initial Review (IR) 2008 Approval (Protocol Version Date 07/14/08)

Documents Posted:

- 11/20/08: CIRB Initial Review Approval Letter (Revised) for Protocol Version Date 07/14/08
- 11/20/08: CIRB Correction to Approval Letter dated 07/18/08

Correction:

The **NCCTG N0723 Initial Review** approval letter dated **July 18, 2008** contains an error. The letter stated that the full Board meeting of the NCI Adult Central IRB (CIRB) took place on **June 27, 2007**. The letter should have stated that the full Board meeting of the NCI Adult Central IRB (CIRB) took place on **June 27, 2008**.

NSABP-B-43

Continuing Review (CR) March 2008 Approval (Protocol Version Date 07/19/07)

Documents Posted:

- 11/14/08: CIRB Corrected Continuing Review Approval Letter dated 3/24/08
- 11/14/08: CIRB Continuing Review Approval Letter (Corrected)

Correction:

The NSABP B-43 Continuing Review approval letter dated March 24, 2008 contains an error. The letter stated that CIRB approval for this protocol will expire



on March 16, 2009. The letter should have stated that **CIRB approval for this protocol will expire on March 17, 2009.**

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.