



NCI Central IRB Study Activity Update

September 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. ******



Other Activity Posted:

CALGB-30607

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

- CIRB Continuing Review Application (Protocol Version Date 05/15/08)
- 09/09/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/15/08)
- 08/07/08: Continuing Review Reminder Notice
- Protocol Version Date 05/15/08
- Informed Consent Document for Protocol Version Date 05/15/08 [Per Sep 08 CR]

COG – AALL0434

Amendment Review (AR): Amendment #2B (Protocol Version Date 08/07/08)
Reactivation
Documents Posted:

- CIRB Application (Protocol Version Date 08/07/08)
- CIRB Application (Protocol Version Date 06/17/08)
- CIRB Application (Protocol Version Date 03/07/08)
- 09/08/08: Study Reactivation Memo (Protocol Version Date 08/07/08)
- 09/05/08: Change Memo (Protocol Version Date 08/07/08)
- 08/29/08: CIRB Amendment #2B Approval Letter (Protocol Version Date 08/07/08)
- 08/07/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/17/08)
- 08/07/08: Approval Pending Modification Letter (Protocol Version Date 06/17/08)
- 06/17/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/17/08)
- 05/02/08: Approval Pending Modification Letter (Protocol Version Date 03/07/08)
- 03/07/08: Change Letter (Protocol Version Date 03/07/08)
- Protocol Version Date 08/07/08
- Protocol Version Date 08/07/08 - Highlighted Changes
- Protocol Version Date 06/17/08
- Protocol Version Date 06/17/08 - Highlighted Changes
- Protocol Version Date 03/07/08
- Protocol Version Date 03/07/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 08/07/08: Part I - Induction Therapy
- Informed Consent Document for Protocol Version Date 08/07/08: Part II - Low Risk



- Informed Consent Document for Protocol Version Date 08/07/08: Part II - Intermediate Risk
- Informed Consent Document for Protocol Version Date 08/07/08: Part II - High Risk
- Informed Consent Document for Protocol Version Date 08/07/08: Part II - Induction Failure
- 04/10/08: Primary Reviewer 1 Comments
- 04/10/08: Minutes - Amendment Review

COG – ACCRN07

Amendment Continuing (AR): Amendment #1 (Protocol Version Date 08/06/08)
Documents Posted:

- CIRB Application (Protocol Version Date 08/06/08)
- 09/08/08: Study Reactivation Memo (Protocol Version Date 08/07/08)
- 08/29/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 08/06/08)
- 08/07/08: Change Letter (Protocol Version Date 08/06/08)
- Protocol Version Date 08/06/08
- Protocol Version Date 08/06/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 08/06/08 - Patient Consent
- Informed Consent Document for Protocol Version Date 08/06/08 - Parental Consent
- Assent Form Document for Protocol Version Date 08/06/08

COG – ACNS0621

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

- CIRB Continuing Review Application (Protocol Version Date 08/13/08)
- 09/04/08: Continuing Review Approval Letter (Protocol Version Date 08/13/08)
- 08/08/08: Continuing Review Reminder Notice
- Protocol Version Date 03/21/08
- Informed Consent Document for Protocol Version Date 08/13/08

COG – ADVL0221

Amendment Review (AR): Amendment #1 (Protocol Version Date 06/30/08) Study
Reactivation at Dose Level #2

Documents Posted:

- CIRB Application (Protocol Version Date 06/30/08)
- 09/08/08: Study Activation Memo (Protocol Version Date 06/30/08)



- 08/27/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 06/30/08)
- 06/30/08: Change Letter (Protocol Version Date 06/30/08)
- Protocol Version Date 06/30/08
- Protocol Version Date 06/30/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 06/30/08

COG – AREN0532

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

- CIRB Continuing Review Application (Protocol Version Date 10/16/07)
- 09/05/08: CIRB Continuing Review Approval Letter (Protocol Version Date 10/16/07)
- 09/02/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/16/07)
- 08/29/08: CIRB Approval Pending Modification Letter (Protocol Version Date 10/16/07)
- 07/11/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/16/07
- Informed Consent Document for Protocol Version Date 10/16/07 - Chemotherapy Arm
- Informed Consent Document for Protocol Version Date 10/16/07 - Observation Arm
- Study Progress Report
- 04/11/08: DSMC Report

COG – ARET0231

Amendment Review (AR): Amendment #2 (Protocol Version Date 06/26/08)

Documents Posted:

- CIRB Application (Protocol Version Date 06/26/08)
- 09/08/08: COG Change Memo (Protocol Version Date 06/26/08)
- 09/05/08: COG Change Memo (Protocol Version Date 06/26/08)
- 08/27/08: CIRB Amendment #2 Approval Letter (Protocol Version Date 06/26/08)
- 06/26/08: COG Change Letter (Protocol Version Date 06/26/08)
- Protocol Version Date 06/26/08
- Protocol Version Date 06/26/08 - Highlighted Version
- Informed Consent Document for Protocol Version Date 06/26/08



ECOG-E1305

Amendment Review (AR): Update 1 August 2008 Approval
Documents Posted:

- CIRB Application (Protocol Version Date 08/08/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/08/08)
- 08/25/08: CIRB Update 1 Approval Letter (Protocol Version Date 08/08/08)
- Protocol Version Date 08/08/08
- Informed Consent Document for Protocol Version Date 08/08/08 [Per Up 1]

ECOG-E2805

Amendment Review (AR): Addendum 4 July 2008 Approval
Documents Posted:

- 3/11/08 Change Memo
- CIRB Application (Protocol Version Date 03/11/08)
- Summary of CIRB Application Revisions (Protocol Version Date 03/11/08)
- 08/15/08: CIRB Addendum 4 Approval Letter (Protocol Version Date 03/11/08)
- ECOG Conflict of Interest Policy
- Protocol Version Date 03/11/08
- Informed Consent Document for Protocol Version Date 03/11/08 [Per Add 4]
- 07/21/08: Minutes - Addendum 4

ECOG-E4402

Amendment Review (AR): ****Closed to Accrual Effective September 12, 2008****
Documents Posted:

- 08/29/08: CIRB Acknowledgement of Receipt - Notification of Closure
- 08/15/08: ECOG Closure Notice

NSABP-B-34

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

- CIRB Continuing Review Application (Protocol Version Date 04/19/07)
- 08/27/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/19/07)
- 07/25/08: NSABP Cover Letter
- 07/14/08: Continuing Review Reminder Notice
- Protocol Version Date 04/19/07
- 04/25/08: DMC Minutes



- 10/12/07: DMC Minutes
- 2007 - Study Summary

NSABP-B-35

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

- CIRB Continuing Review Application (Protocol Version Date 03/26/07)
- 09/05/08: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
- 08/15/08: NSABP Cover Memo
- 07/14/08: Continuing Review Reminder Notice
- Protocol Version Date 03/26/07
- 04/25/08: DMC Minutes
- 2007 Study Summary

RTOG-0126

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

- CIRB Continuing Review Application (Protocol Version Date 09/19/07)
- 09/05/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/19/07)
- 07/14/08: Continuing Review Reminder Notice
- Protocol Version Date 09/19/07
- June 2008 - Study Summary
- 01/11/08: DMC Minutes

RTOG-0412-SWOG-S0332

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

- CIRB Continuing Review Application (Protocol Version Date 02/14/07)
- 09/05/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/14/07)
- 06/06/08: Continuing Review Reminder Notice
- Protocol Version Date 02/14/07
- June 2008 - Study Summary
- 01/11/08: DMC Minutes

SWOG-S0421

Amendment Review (AR): Revision 2 August 2008 Approval
Documents Posted:

- 06/11/08: Change Memo (Protocol Version Date 06/11/08)



- CIRB Application (Protocol Version Date 06/11/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/11/08)
- 08/01/08: CIRB Revision 2 Approval Letter (Protocol Version Date 06/11/08)
- Protocol Version Date 06/11/08
- Informed Consent Document for Protocol Version Date 06/11/08 [Per Rev 2]

SWOG-S0421

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

- CIRB Continuing Review Application (Protocol Version Date 06/11/08)
- 09/05/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/11/08)
- 07/14/08: Continuing Review Reminder Notice
- Protocol Version Date 06/11/08
- Informed Consent Document for Protocol Version Date 06/11/08 [Per Sep 08 CR]
- 05/02/08: DSMC Minutes
- May 2008 - Study Summary

Serious Adverse Events

Study: ACOSOG Z1031

SAE Posted: 1221289, 1915459

Study: CALGB 30607

SAE Posted: Investigator Notification

Study: CALGB 80203

SAE Posted: DDL#251 FU1/ 07-02-12107, DDL#255/07-02-12571

Study: CALGB 80303

SAE Posted: 240959 FU1, 1024316

Study: CALGB 90401

SAE Posted: 240959 FU1, 1024316

Study: CALGB ECOG 100104

SAE Posted: 062-C5013-07060825, 1158643

Study: CALGB SWOG C80405

SAE Posted: 08-02-14426, 240959 FU1, DDL#251 FU1/ 07-02-12107



Study: ECOG E1105
SAE Posted: 1696275, 240959 FU1, 1024316

Study: ECOG E1305
SAE Posted: 240958, 1024316

Study: ECOG E 1505
SAE Posted: 1696275, 240959 FU1, 1024316

Study: ECOG E1A05
SAE Posted: 062-C5013-07060825, 1158643

Study: ECOG E1A06
SAE Posted: 062-C5013-07060825, 1158643

Study: ECOG E2100
SAE Posted: 1696275, 240959 FU1, 1024316

Study: ECOG E2805
SAE Posted: Investigator Notification

Study: ECOG E3200
SAE Posted: 240959 FU1, 1254692, 1024316

Study: ECOG E4599
SAE Posted: 240959 FU1, 1024316

Study: ECOG E4A03
SAE Posted: 062-C5013-07060825, 1158643

Study: ECOG E5103
SAE Posted: 240959 FU1, 1024316

Study: ECOG E5202
SAE Posted: 240959 FU1, 1024316

Study: ECOG E5204
SAE Posted: 240959 FU1, 1024316

Study: GOG 0213
SAE Posted: 1024316

Study: GOG 0218
SAE Posted: 1024316



Study: NCCTG N0147
SAE Posted: 08-02-14426, DDL#255/07-02-12571

Study: NSABP B-34
SAE Posted: 200811207 SU92, 200818690 SU90, 200819168 SU91, 200824407 SU93

Study: NSABP B-38
SAE Posted: MX200806001694

Study: NSABP B-40
SAE Posted: 262431, MX200806001694, 1024316, 250334 FU1

Study: NSABP C-08
SAE Posted: 261116, 262431, 240959 FU1, 1024316, 248750 FU2

Study: RTOG 0320
SAE Posted: 2007SP000310, 2007SP001239, 2007SP018230 FU6, 2008SP001606, 2008SP001606 FU1, 2008SP001606 FU2, 2008SP006508, 2008SP009302, 2008SP009306,

Study: RTOG 0436
SAE Posted: 08-02-14426, DDL#251 FU1/ 07-02-12107, 1024316, DDL#255/07-02-12571

Study: RTOG 0522
SAE Posted: 08-02-14121, 08-02-14121 FU1, 08-02-14164, 08-02-14213, 08-02-14272, 08-02-14426, DDL#253/07-02-12427, DDL#254/07-02-12430

Study: RTOG 0525
SAE Posted: 2007SP000310, 2007SP001239, 2007SP018230 FU6, 2008SP001606, 2008SP001606 FU1, 2008SP001606 FU2, 2008SP006508, 2008SP009302, 2008SP009306, 2007SP007552 FU4, 2007SP007552 FU5, 2007SP020934, 2007SP007552 FU7

Study: SWOG S0232
SAE Posted: 062-C5013-07060825

Study: SWOG S0502
SAE Posted: 240959 FU1, 1024316

Study: SWOG S0232
SAE Posted: 1158643

Study: SWOG S0600
SAE Posted: 08-02-14426, 240959 FU1, 1024316, DDL#255/07-02-12571



Corrections to Previous Study Activity Updates

ECOG-E3201

Amendment Review (AR): Addendum #5 Approval August 2008
Documents Posted:

08/27/08: CIRB Acknowledgement of Posting (Protocol Version Date 06/26/08)

Correction: The date of this acknowledgement letter was originally posted as 8/22/08. The correct date is 8/27/08.

NCCTG-N0147

Amendment Review (AR): Addendum #9 Approval August 2008
Documents Posted:

08/01/08: CIRB Addendum 9 Approval Letter (Protocol Version Date 07/21/08)

Correction: *Addendum 9 Approval Letter* was incorrectly listed as *Amendment 1 Approval Letter*.

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.