



NCI Central IRB Study Activity Update

May 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:

ACOSOG-Z4032

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/15/08)
- 05/05/08: CIRB Continuing Review Approval Letter May 2008 (Protocol Version Date 02/15/08)
- 02/14/08: CIRB Continuing Review Reminder Notice for May 2008
- Protocol Version Date 02/15/08
- Informed Consent Document for Protocol Version Date 02/15/08 [per May 08 CR]
- 08/17/07: DSMB Minutes
- Study Summary

CALGB-80101

Continuing Review (CR) Approval April 2008

Documents Posted:

- 04/21/08: Minutes: Continuing Review 2008

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

CALGB-100104-ECOG-100104

Continuing Review (CR) Approval May 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/11/07)
- 05/05/08: CIRB Continuing Review Approval Letter May 2008 (Protocol Version Date 06/11/07)
- 02/14/08: CIRB Continuing Review Reminder for May 2008
- Protocol Version Date 06/11/07
- Informed Consent Document for Protocol Version Date 06/11/07 [Per May 08 CR]
- 01/15/08: DSMB Statements
- 12/21/07: DSMB Report
- Study Summary Dated November 2007



COG – AALL0331

Acknowledgement of Memo re AALL0331 Temporary Suspension of Enrollment (05/02/08)

Documents Posted:

- 05/05/08: CIRB Acknowledgement of AALL0331 Temporary Suspension of Enrollment
- 05/02/08: AALL0331 Temporary Suspension of Enrollment

COG – AALL03B1

Acknowledgement of Suspension of Enrollment of High-Risk B-precursor Patients (04/25/08)

Documents Posted:

- 05/01/08: CIRB Acknowledgement of AALL03B1 Temporary Suspension of Enrollment of High-Risk B-precursor Patients
- 04/25/08: AALL03B1 Temporary Suspension of Enrollment of High-Risk

Acknowledgement of Memo re AALL03B1 Temporary Partial Closure to Accrual for Non-Infant B-precursor ALL Patients and T-cell Patients (05/05/08)

Documents Posted:

- 05/07/08: CIRB Acknowledgement of Temporary Closure to Accrual for AALL03B1
- 05/05/08: AALL03B1 Temporary Suspension of Enrollment of Non-Infant B-precursor ALL Patients

COG – AALL05B1

Continuing Review (CR): Continuing Review April 2008

Documents Posted:

- 04/10/08: Primary Reviewer 1 Comments
- 04/10/08: 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 – AALL0434

Acknowledgement of Memo re AALL0434 Temporary Suspension of Enrollment (05/02/08)

Documents Posted:

- 05/05/08: CIRB Acknowledgement of AALL0434 Temporary Suspension of Enrollment
- 05/02/08: AALL0434 Temporary Suspension of Enrollment



COG – ACNS0232

Continuing Review (CR): Continuing Review March 2008

Documents Posted:

- 03/13/08: Primary Reviewer 1 Comments
- 03/13/08: 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 – ANBL0421

Continuing Review (CR): Continuing Review April 2008

Documents Posted:

- 04/10/08: Primary Reviewer 1 Comments
- 04/10/08: 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 – ANBL0531

Continuing Review (CR): Continuing Review January 2008

Documents Posted:

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: 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 – ANBL0532

Continuing Review (CR): Continuing Review January 2008

Documents Posted:

- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: 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 – AHOD04B1

Continuing Review (CR): Continuing Review February 2008

Documents Posted:

- 02/14/08: Primary Reviewer 1 Comments
- 02/14/08: 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 – AHOD0521

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

- 02/14/08: Primary Reviewer 1 Comments
- 02/14/08: Minutes - Continuing Review

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

Acknowledgement of Temporary Closure to Accrual for AHOD0521 (04/28/08)
Documents Posted:

- 05/14/08: CIRB Acknowledgement of Temporary Closure to Accrual for AHOD0521
- 05/02/08: AHOD0521 Temporary Suspension of Enrollment

COG – AEWS0621

Acknowledgement of AEWS0621 Study Closure (05/02/08)
Documents Posted:

- 05/05/08: CIRB Acknowledgement of AEWS0621 Study Closure
- 05/02/08: Closure of AEWS0621

ECOG-E1900

RE-OPENED TO ACCRUAL, as of April 29, 2008

ECOG-E2100

Amendment Review (AR) Addendum #10 Approval January 2007
Documents Posted:

- CIRB Application Version 06/22/06
- Summary of CIRB Application Revisions
- 01/03/07: CIRB Addendum #10 Approval (Protocol Version Date 10/23/06)
- 10/23/06: ECOG Response to Approval Pending Modification
- 08/21/06: CIRB Addendum #10 Approval Pending Modification (Protocol Version Date 06/22/06)
- 08/09/06: CIRB Addendum #10 Approval (Protocol Version Date 06/22/06)
- Informed Consent Document for Protocol Version Date 10/23/06

Note: **Closed to Accrual- Effective May 26, 2004**



NCCTG-N0147

Amendment Review (AR) Addendum #8 Approval April 2008
Documents Posted:

- Change Memo (Protocol Version Date 01/31/08)
- CIRB Application Version 01/31/08
- Summary of CIRB Application Revisions
- 05/09/08: Group Correction Memo
- 05/09/08: CIRB Acknowledgement of Receipt of Revised Changes (Protocol Version Date 01/31/08)
- 04/17/08: CIRB Addendum #8 Approval April 2008 (Protocol Version Date 01/31/08)
- Protocol Version Date 01/31/08 [per Add 8]
- Appendices for Protocol Version Date 01/31/08
- Informed Consent Document for Protocol Version Date 01/31/08 [per Add 8 AR]
- 04/04/08: Primary Reviewer 1 Comments
- 04/04/08: Minutes Addendum #8 Review

SWOG-S0427

Continuing Review (CR) May 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/02/07)
- 05/13/08: CIRB Approval of Administrative Closure (Protocol Version Date 03/02/07)
- 02/14/08: CIRB Continuing Review Reminder Notice for May 2008
- Protocol Version Date 03/02/07
- Toxicity Summary

Note: **Administratively Closed – Effective May 13, 2008**



Serious Adverse Events

Study: COG ADVL 0525

AE Posted: CN200711005186, CN200711005186(1), IN200701006175, IN200712005086, US200712004401, BE200710004138(1), HU200708001668(1), CA200708001635(1)

Study: COG ARST 0531

AE Posted: 1893079

Study: COG ARST 0332

AE Posted: 1893079

Study: COG ADVL 0524

AE Posted: 07-02-12571, 1940244(1)

Study: ACOSOG Z1031

AE Posted: 1997021, 1136287

Study: NCIC CTG MA.27

AE Posted: MA27-21 FU1, MA27-24

Study: ECOG E1105

AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E1305

AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E1505

AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 255513, 250945(2),

Study: ECOG E2100

AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E2603

AE Posted: 1829917

Study: ECOG E2805

AE Posted: 253339, 1165164, 1829917

Study: ECOG E2902

AE Posted:



Study: ECOG E3201
AE Posted: 1928581

Study: ECOG E4599
AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E5103
AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E5202
AE Posted: 253339, 250866(2), 1165164, 1928581, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E5204
AE Posted: 253339, 250866(2), 1165164, 1928581, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: ECOG E6201
AE Posted: 1928581

Study: GOG 0213
AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: GOG 0218
AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: CALGB 80203
AE Posted: 1928581, 1435303, 08-02-13848, 08-02-13884

Study: CALGB 80303
AE Posted: 253339, 250866(2), 1165164, 252935(1), 07-02-13307(3), 250945, 1435303, 1459647, 255513, 250945(2),

Study: CALGB 90206
AE Posted: 253339, 250866(2), 1165164, 252935(1) , 1435303, 255513, 250945(2),



Study: CALGB 90401

AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: NSABP C-08

AE Posted: 253089, 253192, 253339, 1165164, 1928581, 250367(5), 253089(1), 254163, 250945 , 1435303, 1459647, 255513, 250945(2), 253339 FU1, 257028, 257362, 254163 FU2, 255513 FU2

Study: NSABP C-09

AE Posted: 1928581

Study: NSABP R-04

AE Posted: 1928581

Study: NSABP B-38

AE Posted: FR200802001087 FU1, GB200711004216 FU2

Study: NSABP B-34

AE Posted: 200810824 Safety Update #70, 200811720 Safety Update #71, 200813728 Safety Update #75, Safety Update #76, 200711360 Safety Update #69 FU3, 200715690 Safety Update #67 FU1, 200813940 Safety Update #77, 200814162 Safety Update #78, 200815097 Safety Update #79

Study: NSABP B-40

AE Posted: 253089, 253192, 253339, 1165164, 250367(5), 253089(1), 254163, 250945 , 1435303, 1459647, 255513, 250945(2), FR200802001087 FU1, GB200711004216 FU2, 253339 FU1, 257028, 257362, 254163 FU2, 255513 FU2

Study: RTOG 0522

AE Posted: 07-02-13577(1), 07-02-13583, 07-02-13307(3) , 1435303, 08-02-13848, 08-02-13884, 05-02-05850(2), 07-02-13583(1), 08-02-13981, 08-02-13989

Study: RTOG 0320

AE Posted: 2006-04-1447(1), 2007SP018230(3), 2007SP014751, 2008SP002006(1), 2007SP018230(4), 2008SP001728(1), 2007SP007552(1), 2008SP003086, 2007SP007552 FU8,

Study: RTOG 0525

AE Posted: 2006-04-1447(1), 2007SP018230(3), 2007SP014751, 2008SP002006(1), 2007SP018230(4), 2008SP001728(1), 2007SP007552(1), 2008SP003086, 2007SP007552 FU8,

Study: RTOG 0436

AE Posted: 07-02-13307(3) , 1435303, 08-02-13848, 08-02-13884

Study: NCCTG N0147



AE Posted: 1928581, 07-02-13172(1), 07-02-13307(3) , 1435303, 08-02-13848, 08-02-13884, 08-02-13981, 08-02-13989

Study: SWOG S0502

AE Posted: 253339, 250866(2), 1165164, 252935(1), 250945 , 1435303, 1459647, 255513, 250945(2),

Study: SWOG S0205

AE Posted: 07-02-13307(3)

Study: SWOG S0518

AE Posted: 253339, 250866(2), 1165164, 252935(1) , 250945, 1435303, 1459647, 255513, 250945(2),

Study: SWOG S0307

AE Posted: DE-2006-032513/Safety Update #41(4)

Study: SWOG S0600

AE Posted: 253339, 250866(2), 1165164, 252935(1), 07-02-13172(1), 07-02-13307(3) , 250945, 1435303, 1459647, 255513, 250945(2), 08-02-13848, 08-02-13884

Permanently Closed Studies, Re-Posted for your Convenience

ACOSOG-Z9031

Completed (No Further Activity Being Conducted) as of February 27, 2006

SWOG-S0347

Completed (No Further Activity Being Conducted) as of February 1, 2006

Corrections to Previous Study Activity Updates

ECOG-E4A03

Amendment Review (AR) Update #2 Approval June 2007

Documents Posted:

01/21/08: CIRB ERRATUM Letter (Protocol Version Date 05/30/07)

Correction:

The ECOG E4A03 Update #2 approval letter dated June 26, 2007 contains an error in the approval date. The ECOG E4A03 Update #2 was approved on June 11, 2007 not on August 19, 2007.



ECOG-E1105

Amendment Review (AR) Addendum #2 Approval November 2007

Documents Posted:

CIRB Application Protocol Version Date 08/24/07

Correction:

CIRB Application was inadvertently not posted with other documents for Addendum #2.

SWOG-0600

Continuing Review (CR) Review Approval April 2008

Documents Posted:

05/06/08: CIRB ERRATUM Letter (Protocol Version Date 09/27/07)

Correction:

The approved protocol version date should read September 27, 2007 **not** September 9, 2007 as stated in the body of the Outcome Letter. The CIRB reviewed and approved Protocol Version Date: September 27, 2007 during its continuing review.

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.