



NCI Central IRB Study Activity Update May 31, 2007

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 - 40101

Amendment Review (AR): Update #7 (Protocol Version Date 02/20/07)

Documents Posted:

- Summary of CIRB Application Revisions
- 04/15/07: Protocol Revisions Update
- CIRB Application (Protocol Version Date 02/20/07)
- 04/17/07: Approval Letter
- Protocol Version Date 02/20/07
- Informed Consent Form for Protocol Version Date 02/20/07

CALGB - 40302

Amendment Review (AR): Update #1 (Protocol Version Date 03/28/07)

Documents Posted:

- Summary of CIRB Application Revisions
- 04/15/07: Protocol Revisions Update
- CIRB Application (Protocol Version Date 03/28/07)
- 04/19/07: Approval Letter
- Protocol Version Date 03/28/07
- Informed Consent Form for Protocol Version Date 03/28/07

CALGB - 50303

Continuing Review (CR) November 2006

Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

Amendment Review (AR) Update #3 November 2006

Documents Posted:

- 11/20/06: Minutes: Amendment Review

CALGB - 80101

Continuing Review (CR) November 2006

Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006



CALGB - 80203

Amendment Review (AR): Update #5 (Protocol Version Date 02/09/07)
Documents Posted:

- 04/15/07: Protocol Revisions Update
- 04/17/07: Approval Letter
- Protocol Version Date 02/09/07
- 04/06/07: Minutes: Update #5 Review

CALGB - 80303

Amendment Review (AR): Update #8 (Protocol Version Date 01/22/07)
Documents Posted:

- 04/15/07: Protocol Revisions Update
- 04/19/07: Approval Letter
- Protocol Version Date 01/22/07

CALGB - 90202

Continuing Review (CR) October 2006
Documents Posted:

- 10/06/06: Minutes: Continuing Review October 2006

CALGB - 90206

Amendment Review (AR): Update #7 December 2006
Documents Posted:

- 12/01/06: Minutes: Amendment Review

CALGB – 100104/ECOG - 100104

Amendment Review (AR): Update #5 (Protocol Version Date 04/09/07)
Documents Posted:

- Summary of CIRB Application Revisions
- 05/15/07: Protocol Revisions Update
- CIRB Application (Protocol Version Date 04/09/07)
- 05/09/07: Approval Letter
- 04/18/07: Group Response Letter
- 04/06/07: Approval Pending Modification
- Protocol Version Date 04/09/07
- Protocol Version Date 02/23/07
- Informed Consent Form for Protocol Version Date 04/09/07
- 03/19/07: Minutes: Amendment #5 Review



COG – AALL0433

Amendment Review (AR) November 2006
Documents Posted:

- 11/30/06: Amendment Review Minutes

COG – AALL06N1

Initial Review (IR) October 2006
Documents Posted:

- 10/26/06: Initial Review Minutes

COG – AAML0531

Continuing Review (CR) November 2006
Documents Posted:

- 11/30/06: Continuing Review Minutes

COG – ACCL04C2

Continuing Review (CR) October 2006
Documents Posted:

- 10/12/06: Continuing Review Minutes

COG – ACNS0221

Continuing Review (CR) October 2006
Documents Posted:

- 10/12/06: Continuing Review Minutes

COG – ADVL0524

Continuing Review (CR) November 2006
Documents Posted:

- 11/30/06: Continuing Review Minutes

COG – AEWS0621

Initial Review (IR) October 2006
Documents Posted:

- 02/08/07: Group Response to Initial Review Minutes
- 10/12/06: Initial Review Minutes



COG – AHOD03P1

Continuing Review (CR) October 2006

Documents Posted:

- 10/12/06: Continuing Review Minutes

COG – AHOD04B1

Amendment Review (AR): Amendment #1 (Protocol Version Date 04/30/07)

Documents Posted:

- CIRB Application (Protocol Version Date 04/30/07)
- 05/11/07: Approval Letter
- Protocol Version Date 04/30/07
- Protocol Version Date 04/30/07, Highlighted
- Informed Consent Form for Protocol Version Date 04/30/07

COG – AHOD0431

Continuing Review (CR) October 2006

Documents Posted:

- 10/26/06: Continuing Review Minutes

COG – AHOD0521

Amendment Review (AR): Amendment #1 (Protocol Version Date 05/01/07)

Documents Posted:

- CIRB Application (Protocol Version Date 05/01/07)
- 05/11/07: Approval Letter
- 05/01/07: Group Response Letter
- Protocol Version Date 05/01/07
- Protocol Version Date 05/01/07, Highlighted Changes
- Informed Consent (Protocol Version Date 05/01/07)

COG – ANBL0322

Amendment Review (AR): Amendment #1 (Protocol Version Date 04/30/07)

Documents Posted:

- CIRB Application (Protocol Version 03/28/07)
- CIRB Application Version 01/17/07
- 05/24/07: Approval Letter
- 05/22/07: CIRB Approval Full Board Letter
- 03/28/07: CIRB Approval Pending Modification
- 03/20/07: CIRB Approval Pending Modification
- 01/17/07: Amendment Letter
- Protocol Version 03/28/07



- Protocol Version 03/28/07, Highlighted - Group Response
- Protocol Version Date 01/17/07
- Protocol Version Date 01/17/07, Highlighted
- Informed Consent for Protocol Version 03/28/07
- 03/08/07: Amendment Review Minutes

COG – AOST0331

Amendment Review (AR): Amendment #1 (Protocol Version Date 10/31/06)
Documents Posted:

- 10/26/06 Amendment Review Minutes

COG – ARAR0331

Continuing Review (CR) October 2006
Documents Posted:

- 10/12/06: Continuing Review Minutes

COG – AREN0321

Continuing Review (CR) October 2006
Documents Posted:

- 10/26/06: Continuing Review Minutes

COG – ARET0231

Continuing Review (CR) March 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/11/06)
- 05/16/07: Approval Letter
- 02/01/07: Continuing Review Notice
- Protocol Version Date 04/11/06
- Informed Consent Form for Protocol Version Date 03/03/07 [Expiration Date updated based on CR March 07]

COG – ARET0331

Continuing Review (CR) October 2006
Documents Posted:

- 11/09/06: Group Response to Tabled Action - Continuing Review Minutes
- 10/12/06: Continuing Review Minutes



COG – ARET0332

Continuing Review (CR) October 2006

Documents Posted:

- 10/26/06: Group Response To Tabled Action - Continuing Review Minutes

COG – ARST0531

Amendment Review (AR) November 2006

Documents Posted:

- 11/30/06: Amendment Review Minutes

ECOG – E1301

Continuing Review (CR) November 2006

Documents Posted:

- 11/20/06: Minutes: Continuing Review November 2006

ECOG – E1Y03

Continuing Review (CR) November 2006

Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

ECOG – E2805

Continuing Review (CR) October 2006

Documents Posted:

- 10/16/06: Minutes: Continuing Review October 2006

ECOG – E3200

Continuing Review (CR) November 2006

Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

ECOG – E3999

Continuing Review (CR) October 2006

Documents Posted:

- 10/06/06: Minutes: Continuing Review October 2006



ECOG – E4402

Amendment Review (AR): Addendum #3 (Protocol Version Date 07/28/06)
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 07/28/06)
- 09/27/06: Approval Letter
- 07/28/06: Addendum to CTEP Memo
- Protocol Version Date 07/28/06
- Informed Consent Form for Protocol Version Date 07/28/06
- 09/01/06: Primary Reviewer 1 Comments

Continuing Review (CR) November 2006
Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

ECOG – E4599

Continuing Review (CR) November 2006
Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

ECOG – E4A03

Continuing Review (CR) November 2006
Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

ECOG – E5204

Continuing Review (CR) October 2006
Documents Posted:

- 10/06/06: Minutes: Continuing Review October 2006

ECOG – PACCT-1

Continuing Review (CR) November 2006
Documents Posted:

- 11/20/06: Minutes: Continuing Review November 2006



GOG – 0212

Amendment Review (AR) Revision #3 October 2006
Documents Posted:

- 10/06/06: Minutes: Amendment Review

Continuing Review (CR) October 2006
Documents Posted:

- 10/06/06: Minutes: Continuing Review October 2006

NCCTG – N0147

Continuing Review (CR) October 2006
Documents Posted:

- 10/20/06: Minutes: Continuing Review October 2006

NCI CTG – MA.27

Continuing Review (CR) May 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/03/06)
- 05/14/07: Approval Letter
- Protocol Version Date 11/03/06
- Informed Consent Form for Protocol Version Date 11/03/06
- 10/19/06: DMC Minutes
- Study Summary

Amendment Review (AR) Amendment #7 November 2006
Documents Posted:

- 11/20/06: Minutes: Amendment Review

NCI CTG – MA.27B

Continuing Review (CR) October 2006
Documents Posted:

- 10/06/06: Minutes: Continuing Review October 2006

NSABP-B-33

Amendment Review (AR): Amendment #6 (Protocol Version Date 03/26/07)
Documents Posted:

- Summary of Protocol Changes



- 05/14/07: Approval Letter
- Protocol Version Date 03/26/07

NSABP-B-36

Amendment Review (AR): Amendment #4 (Protocol Version Date 04/20/07)
Documents Posted:

- Summary of Protocol and Consent Form Changes
- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 04/20/07)
- 05/14/07: Approval Letter
- Protocol Version Date 04/20/07
- Informed Consent Form for Protocol Version Date 04/20/07

NSABP – C - 08

Continuing Review (CR) November 2006
Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

RTOG – H - 0129

Continuing Review (CR) November 2006
Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

RTOG – 0232

Amendment Review (AR): Amendment #3 (Protocol Version Date 01/24/07)
Documents Posted:

- Summary of Changes
- CIRB Application (Protocol Version Date 01/24/07)
- 04/20/07: Approval Letter
- Protocol Version Date 01/24/07
- Protocol Version Date 01/24/07, Tracked
- Main Informed Consent Form for Protocol Version Date 01/24/07
- Cost Data Informed Consent Form for Protocol Version Date 01/24/07
- Tissue Use Informed Consent Form for Protocol Version Date 01/24/07

RTOG – 0320

Continuing Review (CR) November 2006
Documents Posted:

- 11/20/06: Minutes: Continuing Review November 2006



RTOG – 0412/SWOG - 0332

Continuing Review (CR) November 2006

Documents Posted:

- 11/10/06: Minutes: Continuing Review November 2006

RTOG – 0421

Continuing Review (CR) October 2006

Documents Posted:

- 10/20/06: Minutes: Continuing Review October 2006

RTOG – 0525

Continuing Review (CR) October 2006

Documents Posted:

- 10/06/06: Minutes: Continuing Review October 2006

SWOG – S0012

Continuing Review (CR) November 2006

Documents Posted:

- 11/06/06: Minutes: Continuing Review November 2006

SWOG – S0124

Continuing Review (CR) May 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/16/07)
- 05/14/07: Approval Letter
- Protocol Version Date 01/16/07
- Addendum A - Consent Form
- Addendum B - SAE Listing
- Addendum C - DSMB Report
- Addendum D - Toxicity Summary

Amendment Review (AR) Amendment #2 November 2006

Documents Posted:

- 11/20/06: Minutes: Amendment Review

SWOG – S0221

Amendment Review (AR) Amendment #4 October 2006

Documents Posted:

- 10/20/06: Minutes: Amendment Review



SWOG – S0232

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

- 05/18/07: CIRB Acknowledgement of Receipt
- 05/15/07: Study Closure Notification

SWOG – S0427

Amendment Review (AR) Revision #2 October 2006
Documents Posted:

- 10/20/06: Minutes: Amendment Review

Serious Adverse Events

Study: ACOSOG-Z1031

SAE's Posted: ACOSOG-Z1031_1258923

Study: ECOG E2805

SAE Posted: 1007443, 1333296

Study: NSABP B-34

SAE's Posted: DE-2006-032513 / Safety Update # 41 (1), GB-2006-040116 / Safety Update # 39 (2)

Study: NSABP B-38

SAE's Posted: DE2007001788, GB200702004646, US200604004743 (1)

Study: NSABP B-40

SAE's Posted: DE2007001788, GB200702004646, US200604004743 (1)

Study: RTOG 0320

SAE's Posted: 2007SP003140 (3), 2007SP003140 (4)

Study: RTOG 0522

SAE's Posted: DDL # 243 (1) / 07-02-11207, DDL # 245 / 06-02-10323, DDL # 246 / 07-02-11278, DDL # 247 / 07-02-11452

Study: RTOG 0525

SAE's Posted: 2007SP003140 (3), 2007SP003140 (4)

Study: SWOG S0200

SAE Posted: 20070201421 (0)



Study: SWOG S0205

SAE's Posted: DDL # 243, DDL # 243 (1) / 07-02-11207, DDL # 244, DDL # 245 / 06-02-10323, DDL # 246 / 07-02-11278, DDL # 247 / 07-02-11452

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.