



NCI Central IRB Study Activity Update July 16, 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. ******

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.

Adult CIRB Studies

CALGB - 140503

Initial Review 2007

Documents Posted:

- Protocol Version Date 04/13/07
- Protocol Version Date 12/29/06
- Informed Consent Form for Protocol Version Date 04/13/07
- CIRB Application (Protocol Version Date 12/29/06)
- 05/04/07: Primary Reviewer 1 Comments
- 02/12/07: Primary Reviewer 1 Comments
- 12/29/06: Group Response Letter
- 05/10/07: Final Approval Letter
- 03/21/07: CIRB Table of Initial Review
- 04/13/07: Group Response to CIRB
- 02/12/07: Minutes: Initial Review

Other Activity Posted:

ACOSOG – Z4032

Continuing Review (CR) June 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/11/05)
- 07/09/07: Approval Letter
- Protocol Version Date 04/11/05
- Informed Consent Form for Protocol Version Date 04/11/05
[Per June 06 CR]
- 06/22/06: DMC Minutes
- Study Summary

CALGB - 40101

Continuing Review (CR) September 2006

Documents Posted:

- 09/18/06: Minutes: Continuing Review



CALGB - 80303

Amendment Review (AR): Update #6
Documents Posted:

- 09/18/06: Minutes: Amendment Review

CALGB - 90206

Amendment Review (AR): Update #8
Documents Posted:

- Summary of Changes

CALGB - 90401

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

COG-ANBL0421

Continuing Review (CR) June 2007
Documents Posted:

- CIRB Continuing Review Application for 2007
- 06/20/07, CIRB Approval to Continuing Review June 2007 (Protocol Version 04/01/06)
- Protocol Version Date 04/01/06
- Informed Consent for Protocol Version Date 04/01/06 [per June 2007 CR]
- Study Progress Report Dated 03/30/07

COG-AOST0331

Continuing Review (CR) June 2007
Documents Posted:

- CIRB Continuing Review Application Protocol Version Date 10/31/06
- 07/13/07, CIRB Approval to Continuing Review June 2007
- 06/28/07, CIRB Table Letter for Continuing Review
- Protocol Version Date 10/31/06
- Informed Consent for Protocol Version Date 10/31/06: Part 1: Induction Therapy
- Informed Consent for Protocol Version Date 10/31/06: Part 2: Good Response
- Informed Consent for Protocol Version Date 10/31/06: Part 2: Poor Response
- Accrual Report for June 2007 Continuing Review
- International DMC Letter for June 2007 Continuing Review



- Toxicity Report June 2007 Continuing Review

ECOG – E1505

Amendment Review (AR): Update #2

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 06/01/07)
- 06/01/07: Letter from the Group
- 06/26/07: Approval Letter
- Protocol Version Date 06/01/07
- Informed Consent Form for Protocol Version Date 06/01/07

Amendment Review (AR): Addendum #2

Documents Posted:

- 09/18/06: Minutes: Amendment Review

ECOG – E1900

Continuing Review (CR) September 2006

Documents Posted:

- 09/18/06: Minutes: Continuing Review

ECOG – E2603

Amendment Review (AR): Update #3

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 05/16/07)
- 06/06/07: Approval Letter
- 05/16/07: Group Response Letter
- Protocol Version Date 05/16/07
- Informed Consent Form for Protocol Version Date 05/16/07

Frequently Asked Question (FAQ) for ECOG E2603

- Fact Sheet about ECOG E2603
- 04/23/07: CIRB Approval of the Frequently Asked Question (FAQ)



ECOG – E3200

Amendment Review (AR): Update #1
Documents Posted:

- 06/20/07: Approval Letter
- 03/07/07: Group Response Letter
- Protocol Version Date 03/07/07

ECOG – E3201

Amendment Review (AR): Update #2
Documents Posted:

- 06/19/07: Approval Letter
- 03/07/07: Group Response Letter
- Protocol Version Date 03/07/07

ECOG – E4201

Amendment Review (AR): Update #2
Documents Posted:

- 06/20/07: Approval Letter
- 03/07/07: Group Response Letter
- Protocol Version Date 03/07/07

ECOG – E4402

Amendment Review (AR): Addendum #3
Documents Posted:

- 09/18/06: Minutes: Amendment Review

ECOG – E5204

Recruitment Materials for ECOG E5204
Documents Posted:

- Fact Sheet about E5204
- 06/21/07: CIRB Approval of Recruitment Materials for ECOG E5204

ECOG – E6201

Amendment Review (AR): Update #1
Documents Posted:

- 06/20/07: Approval Letter
- 03/07/07: Study Update Letter
- Protocol Version Date 03/07/07



GOG – 0198

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

GOG – 0204

Amendment Review (AR): Revision #5
Documents Posted:

- 08/21/06: Minutes: Amendment Review

GOG – 0212

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

- 07/17/06: Minutes: Amendment Review

NCIC CTG – MA.27

Continuing Review (CR) May 2007
Documents Posted:

- 05/04/07: Primary Reviewer 1 Comments

Continuing Review (CR) July 2006
Documents Posted:

- 07/17/06: Minutes: Continuing Review

NCIC CTG – N0574

Amendment Review (AR): Addendum #1
Documents Posted:

- Summary of CIRB Application Revisions
- Summary of Protocol Changes
- CIRB Application (Protocol Version Date 04/17/07)
- 05/03/07: Approval Letter
- 04/06/07: CIRB Approval Pending Modification
- Protocol Version Date 04/17/07
- Protocol Version Date 02/08/07
- Informed Consent Form for Protocol Version Date 04/17/07
- 03/19/07: Primary Reviewer 1 Comments
- 03/19/07: Minutes: Amendment Review



NSABP – B - 34

Amendment Review (AR): Amendment #11
Documents Posted:

- Summary of Protocol Changes in NSABP B-34
- 06/06/07: Approval Letter
- Protocol Version Date 04/19/07

NSABP – B - 38

Amendment Review (AR): Amendment #3
Documents Posted:

- CIRB Application Revision Summary
- Summary of Protocol Changes
- CIRB Application (Protocol Version Date 04/17/07)
- 06/06/07: Approval Letter
- Protocol Version Date 04/17/07

Amendment Review (AR): Study Closure
Documents Posted:

- 07/03/07: CIRB Acknowledgement of Receipt
- 03/22/07: Closure Notice

RTOG – 0214

Continuing Review (CR) July 2006
Documents Posted:

- 07/17/06: Minutes: Continuing Review

RTOG – 0421

Amendment Review (AR): Amendment #1
Documents Posted:

- 09/01/06: Minutes: Amendment Review

RTOG – 0521

Amendment Review (AR): Amendment #3
Documents Posted:

- Summary of CIRB Application Revisions
- Summary of Protocol Changes
- CIRB Application (Protocol Version Date 04/27/07)
- 06/08/07: Approval Letter



- 04/27/07: Letter from the Group
- Protocol Version Date 04/27/07
- Protocol Version Date 04/27/07 - Tracked
- Informed Consent Form for Protocol Version Date 04/27/07
- Informed Consent Form for Protocol Version Date 04/27/07 – Tissue

Amendment Review (AR): Amendment #1
Documents Posted:

- 09/01/06: Minutes: Amendment Review

RTOG – 0525

Amendment Review (AR): Amendment #2
Documents Posted:

- Appendix IX (EORTC)
- Appendix X (NCCTG) - Tracked
- Appendix X (NCCTG) - Untracked
- Controlled Oral Word Association - Form 1
- Controlled Oral Word Association - Form 2
- Hopkins Verbal Learning Test - Revised (Form 1)
- Hopkins Verbal Learning Test - Revised (Form 2)
- Hopkins Verbal Learning Test - Revised (Form 3)
- Hopkins Verbal Learning Test - Revised (Form 4)
- Hopkins Verbal Learning Test - Revised (Form 5)
- Hopkins Verbal Learning Test - Revised (Form 6)
- Neurocognitive Evaluation Summary Form
- Neurocognitive Tests Discontinued/Not Done
- Summary of CIRB Application Revisions
- Summary of Changes - Protocol Version Date 05/16/07
- Summary of Changes - Protocol Version Date 03/15/07
- Symptom Inventory Cover Sheet
- Trail Making Test
- Trail Making Test Data Summary Form
- QOL EORT QLC 30 (Version 3) Cover Sheet
- Summary of Changes - Update date 09/21/06
- CIRB Application (Protocol Version Date 03/15/07)
- 03/15/07: Group Response Letter
- 06/19/07: Approval Letter
- 05/14/07: CIRB Table of Amendment #2
- Protocol Version Date 05/16/07
- Protocol Version Date 05/16/07 - Tracked
- Protocol Version Date 03/15/07 - Tracked



- Protocol Version Date 03/15/07 - Untracked
- Informed Consent Form for Protocol Version Date 05/16/07
- 04/16/07: Minutes: Amendment Review

SWOG – S0023

Amendment Review (AR): Revision #15
Documents Posted:

- 06/28/07: Approval Letter
- Protocol Version Date 01/16/07

SWOG – S0106

Amendment Review (AR): Revision #4
Documents Posted:

- 09/18/06: Minutes: Amendment Review

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

SWOG – S0124

Continuing Review (CR) May 2007
Documents Posted:

- 05/04/07: Primary Reviewer 1 Comments

Continuing Review (CR) July 2006
Documents Posted:

- 07/17/06: Minutes: Continuing Review

SWOG – S0205

Amendment Review (AR): Amendment #3
Documents Posted:

- 06/20/07: Approval Letter
- Protocol Version Date 02/21/07

SWOG – S0307

Amendment Review (AR): Revision #1
Documents Posted:

- 07/07/06: Minutes: Amendment Review



SWOG – S0309

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

SWOG – S0334

Amendment Review (AR): Permanent Closure Notice
Documents Posted:

- Permanent Closure Notice
- 06/13/07: CIRB Acknowledgement of Receipt

SWOG - S0427

Continuing Review (CR) June 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/02/07)
- 06/26/07: Approval Letter
- Protocol Version Date 03/02/07
- Toxicity Summary

SWOG – S9007

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

SWOG – S9910

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

SWOG – S9925

Continuing Review (CR) September 2006
Documents Posted:

- 09/18/06: Minutes: Continuing Review

Serious Adverse Events

Study: ECOG E2805
SAE Posted: 2006099946



Study: NSABP B-40
SAE Posted: 232344, 232344 (1), 232653 (1), 232653 (2)

Study: NSABP C-08
SAE Posted: 232344 (1), 232653 (1)

Study: RTOG 0522
SAE Posted: DDL # 232 (1) / 06-02-10496 (1), DDL # 248 / 07-02-11537

Study: SWOG S0205
SAE Posted: DDL # 232 (1) / 06-02-10496 (1)

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.