



## NCI Central IRB Study Activity Update August 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](http://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](mailto:ncicirbcontact@emmes.com) or call the CIRB at 888-657-3711.

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### 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](mailto: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>). **\*\***

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### Protocol Specific Documentation (listed by protocol)

**\*\*Note:** All documentation can be accessed through the Participant's Area ([http://www.ncicirb.org/CIRB\\_Login.asp](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:

- 05/04/07: Minutes: Group Response to Initial Review

#### **RTOG - 0617**

Initial Review 2007

Documents Posted:

- Protocol Version Date 08/01/07
- Protocol Version Date 06/11/07
- Patient Swallowing Diary
- Functional Assessment Trial Outcome Index (TOI) Form
- Health Utility Measurement Euro (EQ5D)
- Protocol Version Date 03/29/07
- Protocol Version Date 03/29/07 - tracked
- Informed Consent Form for Protocol Version Date 08/01/07
- CIRB Application (Protocol Version Date 08/01/07)
- Summary of CIRB Application Revisions - Protocol Version Date 08/01/07
- CIRB Application (Protocol Version Date 06/11/07)
- Summary of CIRB Application Revisions - Protocol Version Date 06/11/07
- CIRB Application (Protocol Version Date 03/29/07)
- 08/13/07: CIRB Final Approval
- 08/01/07: Group Response Letter
- 07/27/07: CIRB Approval Pending Modification of the Group Response to the Initial Review
- 06/11/07: Group Response Letter
- 05/23/07: CIRB Approval Pending Modification of Initial Review
- 03/29/07: Group Response Letter
- 07/16/07: Minutes: Group Response to Initial Review
- 05/04/07: Minutes: Initial Review



## **Other Activity Posted:**

### **ACOSOG – Z4032**

Continuing Review (CR): June 2007  
Documents Posted:

- 06/18/07: Minutes: Continuing Review

### **CALGB – 40101**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/06/07: Minutes: Continuing Review

### **CALGB – 49907**

Continuing Review (CR): June 2007  
Documents Posted:

- 06/01/07: Minutes: Continuing Review

### **CALGB – 50303**

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

- 05/21/07: Minutes: Amendment Review

### **CALGB – 80203**

Continuing Review (CR): August 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/09/07)
- 08/20/07: Approval Letter
- Protocol Version Date 02/09/07
- 08/03/07: Minutes: Continuing Review
- AE Report
- Study Summary

### **CALGB – 80303**

Continuing Review (CR): August 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/22/07)
- 08/16/07: Approval Letter
- Protocol Version Date 01/22/07
- 08/03/07: Minutes: Continuing Review



- Study Summary
- AEs Report
- Article - Journal of Clinical Oncology (May 2007)

#### **CALGB/SWOG – 80405**

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

- 05/04/07: Minutes: Amendment Review

#### **CALGB – 90202**

Continuing Review (CR): August 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/02/07)
- 08/20/07: Approval Letter
- Protocol Version Date 02/02/07
- Informed Consent Form for Protocol Version Date 02/02/07  
[per CR Aug 07]
- 08/03/07: Minutes: Continuing Review
- Study Summary

#### **CALGB – 90203**

Continuing Review (CR): August 2007  
Documents Posted:

- CIRB Continuing Review Application - Protocol Version Date 10/31/06
- 08/17/07: Approval Letter
- Protocol Version Date 10/31/06
- Informed Consent Form for Protocol Version Date 10/31/06  
[per CR Aug 07]
- 08/03/07: Minutes: Continuing Review
- Study Summary

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

- Summary of CIRB Application Revisions
- Protocol Update Summary
- CIRB Application (Protocol Version Date 06/14/07)
- 07/17/07: Approval Letter
- Protocol Version Date 06/14/07
- Informed Consent Form for Protocol Version Date 06/14/07



### **CALGB – 90401**

Continuing Review (CR): August 2007  
Documents Posted:

- 08/03/07: Minutes: Continuing Review

### **COG – AALL03B1**

Continuing Review (CR) July 2007  
Documents Posted:

- CIRB Continuing Review Application Version 08/01/06
- 08/23/07: CIRB Approval of Continuing Review - Protocol Version 08/21/07
- 08/21/07: COG Response to CIRB Review
- 07/27/07: CIRB Approval Pending Modification Letter
- Protocol Version Date 08/21/07
- Informed Consent Form for Protocol Version 08/21/07
- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes
- 04/20/07: Spring DSMC Report

### **COG – AALL05B1**

Continuing Review (CR) June 2007  
Documents Posted:

- 06/14/07: Primary Reviewer 1 Comments
- 06/14/07: Continuing Review Minutes

### **COG – AALL0331**

Continuing Review (CR) July 2007  
Documents Posted:

- CIRB Continuing Review Application
- 08/23/07, CIRB Approval to Continuing Review July 2007 (Protocol Version Date 09/25/06)
- 07/31/07, Group Response to Approval Pending Modifications
- 07/20/07, CIRB Approval Pending Modifications to Continuing Review July 2007 (Protocol Version Date 09/25/06)
- Protocol Version Date 09/25/06
- Informed Consent for Protocol Version Date 09/25/06 [Per July 07 CR]: Induction Therapy
- Informed Consent for Protocol Version Date 09/25/06 [Per July 07 CR]: Standard Risk - High
- Informed Consent for Protocol Version Date 09/25/06 [Per July 07 CR]: Standard Risk - Average



- Informed Consent for Protocol Version Date 09/25/06 [Per July 07 CR]: Standard Risk – Low
- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes
- 04/17/07, DSMC Report
- Study Progress Report Dated 03/30/07

#### **COG – ACNS0221**

Continuing Review (CR) August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/15/05)
- 08/29/07: CIRB Approval to Continuing Review August 2007 (Protocol Version Date 11/15/05)
- Informed Consent Form for Protocol Version 11/15/05 [Per Aug. 07 CR]
- 04/17/07: DSMC Report
- Study Progress Report Dated 03/30/07

#### **COG – ACNS0224**

Continuing Review (CR) July 2007

Documents Posted:

- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

#### **COG – ACNS0232**

Continuing Review (CR) May 2007

Documents Posted:

- 05/10/07: Primary Reviewer 1 Comments
- 05/10/07: Continuing Review Minutes

#### **COG – ACNS0334**

Amendment Review (AR) Amendment #1

Documents Posted:

- 07/12/07: Group Response Primary Reviewer 1 Comments
- 07/12/07: Group Response to Amendment Review Minutes

#### **COG – ACNS0423**

Continuing Review (CR) July 2007

Documents Posted:

- CIRB Continuing Review Application Version 06/19/07
- 07/27/07: CIRB Approval Pending Modification Letter



- 08/22/07: COG Response to CIRB Review
- 08/23/07: CIRB Approval of Continuing Review - Protocol Version 02/12/07
- Protocol Version Date 02/12/07
- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

#### **COG – AHOD0431**

Amendment Review (AR) Amendment #1  
Documents Posted:

- 06/14/07: Primary Reviewer 1 Comments
- 06/14/07: Amendment Review Minutes

#### **COG – ANBL00B1**

Continuing Review (CR) July 2007  
Documents Posted:

- CIRB Continuing Review Application Version 08/18/06
- 08/23/07: CIRB Approval of Continuing Review - Protocol Version 08/06/07
- 07/31/07: COG Response Letter to CIRB Review
- 07/24/07: CIRB Approval Pending Modification Letter
- Protocol Version Date 08/06/07
- Informed Consent Form for Protocol Version 08/06/07
- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

#### **COG – ANBL0322**

Continuing Review (CR) July 2007  
Documents Posted:

- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

#### **COG – ANBL0421**

Continuing Review (CR) June 2007  
Documents Posted:

- 06/14/07: Primary Reviewer 1 Comments
- 06/14/07: Continuing Review Minutes

#### **COG – ANHL04B1**

Continuing Review (CR) July 2007 Approval  
Documents Posted:

- CIRB Application Protocol Version Date 08/03/07



- CIRB Application Protocol Version Date 09/19/06
- 08/17/07: Full Board Approval Letter
- 08/03/07: Change Memo
- 07/24/07: CIRB Approval Pending Modification of Continuing Review of ANHL04B1
- Protocol Version Date 08/03/07
- Protocol Version Date 08/03/07 – Highlighted
- Informed Consent Form for Protocol Version Date 08/03/07
- Study Committee Progress Report Dated 03/30/07
- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

#### **COG – AOST0331**

Continuing Review (CR) July 2007

Documents Posted:

- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

Continuing Review (CR) June 2007

Documents Posted:

- 06/14/07: Primary Reviewer 1 Comments
- 06/14/07: Continuing Review Minutes

#### **COG – ARST0431**

Continuing Review (CR) June 2007

Documents Posted:

- 06/14/07: Primary Reviewer 1 Comments
- 06/14/07: Continuing Review Minutes

#### **COG – D9902**

Continuing Review (CR) July 2007

Documents Posted:

- 07/12/07: Primary Reviewer 1 Comments
- 07/12/07: Continuing Review Minutes

#### **ECOG – E1302**

Amendment Review (AR): Step 2 (Arm C) Permanent Closure

Documents Posted:

- Protocol Notice: E1302 Partial Closure
- 08/30/07: CIRB Acknowledgement of Receipt



### **ECOG – E1900**

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

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 06/07/07)
- 07/17/07: Approval Letter
- Protocol Version Date 06/07/07
- Informed Consent Form for Protocol Version Date 06/07/07

Continuing Review (CR) July 2007  
Documents Posted:

- 07/06/07: Minutes: Continuing Review

### **ECOG – E2603**

Continuing Review (CR): June 2007  
Documents Posted:

- 06/01/07: Minutes: Continuing Review

### **ECOG – E2902**

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

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

### **ECOG – E3999**

Continuing Review (CR): August 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/01/05)
- 08/14/07: Approval Letter
- Protocol Version Date 06/01/05
- 08/03/07: Minutes: Continuing Review
- 04/18/06: DMC Minutes
- Study Summary



### **ECOG – E4A03**

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

- 06/26/07: Approval Letter
- Protocol Version Date 05/30/07

### **ECOG – PACCT - 1**

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

- Summary of CIRB Application Revisions - Protocol Version Date 07/16/07
- Summary of CIRB Application Revisions - Protocol Version Date 05/10/07
- CIRB Application (Protocol Version Date 07/16/07)
- CIRB Application (Protocol Version Date 05/10/07)
- 07/18/07: Approval Letter
- 07/16/07: Letter from the Group
- 07/09/07: CIRB Approval Pending Modification
- 05/10/07: Letter from the Group
- Protocol Version Date 07/16/07
- Protocol Version Date 05/10/07
- Informed Consent Form for Protocol Version Date 07/16/07
- 06/18/07: Minutes: Amendment Review

### **GOG - 0198**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/16/07: Minutes: Continuing Review

### **GOG - 0204**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/06/07: Minutes: Continuing Review

### **GOG - 0209**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/06/07: Minutes: Continuing Review



### **GOG - 0218**

Amendment Review (AR): Revision #3

Documents Posted:

- Summary of CIRB Application Revisions - Protocol Version Date 07/13/07
- Protocol Submission Worksheet
- Summary of CIRB Application Revisions - Protocol Version Date 04/05/07
- CIRB Application (Protocol Version Date 07/13/07)
- CIRB Application (Protocol Version Date 04/05/07)
- 07/16/07: ER Approval Letter
- 07/13/07: Group Response Letter to CIRB Approval Pending Modification
- 07/02/07: CIRB Approval Pending Modification
- 06/07/07: Letter from the Group
- 06/05/07: Full Board CIRB Approval Pending Modification
- 04/05/07: Letter from the Group
- Protocol Version Date 07/13/07
- Protocol Version Date 07/13/07-Tracked
- Protocol Version Date 06/07/07
- Protocol Version Date 06/07/07-Tracked
- Protocol Version Date 04/05/07
- Protocol Version Date 04/05/07-Tracked
- Appendix I
- Appendix II
- Appendix III
- Appendix IV
- Appendix V
- Appendix VI
- Appendix VII
- Appendix VIII-Clean
- Appendix VIII - Tracked
- Informed Consent Form for Protocol Version Date 07/13/07
- 05/21/07: Minutes: Amendment Review

### **NCCTG - N0147**

Amendment Review (AR): Update #2

Documents Posted:

- Appendix 1
- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 07/16/07)
- 07/31/07: Approval Letter
- Protocol Version Date 07/16/07
- Informed Consent Form for Protocol Version Date 07/16/07



**NCCTG – N0434 (MA.27D)**

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

- Authorization for Release of Mammograms
- Summary of Changes
- 07/25/07: Approval Letter
- Protocol Version Date 07/03/07
- Informed Consent Form for Protocol Version Date 07/03/07

Continuing Review (CR): June 2007  
Documents Posted

- 06/01/07: Minutes: Continuing Review

**NCIC CTG – MA.27**

Continuing Review (CR): May 2007  
Documents Posted:

- 05/04/07: Minutes: Continuing Review

**NSABP – B40**

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

- Summary of Protocol Changes
- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 05/30/07)
- 06/26/07: Approval Letter
- 06/04/07: Letter from the Group
- Protocol Version Date 05/30/07
- Informed Consent Form for Protocol Version Date 05/30/07

**NSABP – R - 04**

Continuing Review (CR): May 2007  
Documents Posted:

- 05/04/07: Minutes: Group Response to Continuing Review

**RTOG – 0214**

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

- 08/16/07: Closure Notice
- 08/30/07: CIRB Acknowledgement of Receipt



**RTOG – 0421**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/16/07: Minutes: Continuing Review

**RTOG – 0521**

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

- 06/01/07: Minutes: Amendment Review

**RTOG – 0525**

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

- 05/21/07: Minutes: Group Response to Amendment Review

**SWOG – S0106**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/16/07: Minutes: Continuing Review

**SWOG – S0124**

Continuing Review (CR): May 2007  
Documents Posted:

- 05/04/07: Minutes: Continuing Review

**SWOG – S0205**

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

- 06/18/07: Minutes: Amendment Review

**SWOG – S0232**

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

- Summary of CIRB Application Revisions (Protocol Version Date 06/01/07)
- Summary of CIRB Application Revisions (Protocol Version Date 01/11/07)
- CIRB Application (Protocol Version Date 06/01/07)
- CIRB Application (Protocol Version Date 01/11/07)
- 07/16/07: Approval Letter
- 03/21/07: CIRB Approval Pending Modification



- Protocol Version Date 06/01/07
- 07/06/07: Minutes: Group Response to Amendment Review
- 02/12/07: Minutes: Amendment Review

#### **SWOG – S0307**

Continuing Review (CR): June 2007  
Documents Posted:

- 06/01/07: Minutes: Continuing Review

#### **SWOG – S0309**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/16/07: Minutes: Continuing Review

#### **SWOG – S0337**

Amendment Review (AR): Amendment #0  
Documents Posted:

- 06/01/07: Minutes: Amendment Review

#### **SWOG – 9007**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/16/07: Minutes: Continuing Review

#### **SWOG – S9910**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/16/07: Minutes: Continuing Review

#### **SWOG – S9925**

Continuing Review (CR): July 2007  
Documents Posted:

- 07/06/07: Minutes: Continuing Review

### **Serious Adverse Events**

**Study: CALGB 40302**  
**SAE Posted: A0640845B**

**Study: CALGB 100104**



**SAE Posted: 1784436**

**Study: ECOG E2603  
SAE Posted: 1117502**

**Study: ECOG E2805  
SAE Posted: 1117502, 1424482, 1933626, 1982942**

**Study: NSABP B-34  
SAE Posted: DE-2006-032513 / Safety Update # 41 (4)**

**Study: NSABP B-38  
SAE Posted: GB200705006848**

**Study: NSABP B-40  
SAE Posted: GB200705006848**

**Study: SWOG S0200  
SAE Posted: 20070201421 (3), 20070201421 (5)**

**Study: SWOG S0232  
SAE Posted: 1784436**

**Study: SWOG S0307  
SAE Posted: DE-2006-032513 / Safety Update # 41 (3), GB-2007-014121 (1),  
US-2007-019013 / Safety Update # 48**

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## **Corrections to Previous Study Activity Updates**

### **ECOG - E1505**

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

- 08/30/07: Addendum #4 Eratta Letter

Correction: Addendum #4 did include changes to the Informed Consent document.

### **ECOG - E5204**

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

- 06/26/07: Approval Letter



Correction: Protocol Version Date was changed in the Approval Letter from 05/31/07 to 06/06/07.

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](mailto:ncicirbcontact@emmes.com).