



## **NCI Central IRB Study Activity Update**

**November 14, 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](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. **\*\***



## **Other Activity Posted:**

### **COG-AAML0531**

Amendment Review (AR): Acknowledgement of Clarification Regarding FLT3-ITD Allelic Ratio Testing (Protocol Version Date 03/13/08)

Documents Posted:

- 11/06/08: CIRB Acknowledgement of Clarification
- 04/18/08: COG FLT3-ITD Allelic Ratio Testing Memo

### **COG-AAML05P1**

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/26/07)
- 11/07/08: CIRB Continuing Review Approval Letter (Protocol Version Date 07/26/07)
- 11/06/08: CIRB Approval Pending Modification Letter (Protocol Version Date 07/26/07)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 07/26/07
- Informed Consent Document for Protocol Version Date 07/26/07
- 08/25/08: Study Progress Report
- 11/06/08: DSMC Report

### **COG-AEPI05N1**

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Application (Protocol Version Date 10/30/08)
- CIRB Application (Protocol Version Date 10/15/08)
- CIRB Application (Protocol Version Date 07/28/08)
- 10/31/08: CIRB Approval Letter (Protocol Version Date 10/30/08)
- 10/30/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/07/08)
- 10/28/08: CIRB Approval Pending Modification Letter (Protocol Version Date 10/15/08)
- 10/15/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 07/28/08)
- 10/02/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/30/08
- Protocol Version Date 10/30/08 - Highlighted Changes
- Protocol Version Date 10/15/08
- Protocol Version Date 10/15/08 - Highlighted Changes



- Informed Consent Document for Protocol Version Date 10/30/08 - CASE SUBJECTS
- Informed Consent Document for Protocol Version Date 10/30/08 - CONTROL SUBJECTS

Amendment Review (AR): Amendment #2 (Protocol Version Date 10/30/08)  
Documents Posted:

- CIRB Application (Protocol Version Date 10/30/08)
- CIRB Application (Protocol Version Date 10/15/08)
- 10/31/08: CIRB Approval Letter (Protocol Version Date 10/30/08)
- 10/30/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/07/08)
- 10/28/08: CIRB Approval Pending Modification Letter (Protocol Version Date 10/15/08)
- 10/15/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 07/28/08)
- Protocol Version Date 10/30/08
- Protocol Version Date 10/30/08 - Highlighted Changes
- Protocol Version Date 10/15/08
- Protocol Version Date 10/15/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 10/30/08 - CASE SUBJECTS
- Informed Consent Document for Protocol Version Date 10/30/08 - CONTROL SUBJECTS

#### **COG-AEWS0521**

Amendment Review (AR): CIRB Approval of AEWS0521 Amendment #1 (Protocol Version Date 10/13/08)

Documents Posted:

- CIRB Application (Protocol Version Date 10/13/08)
- CIRB Application (Protocol Version Date 10/01/08)
- 10/21/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 10/13/08)
- 10/13/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/13/08)
- 10/10/08: CIRB Approval Pending Modification Letter (Protocol Version Date 10/01/08)
- 09/30/08: COG Change Letter (Protocol Version Date 01/31/08)
- Protocol Version Date 10/13/08
- Protocol Version Date 10/13/08 - Highlighted Changes
- Protocol Version Date 10/01/08
- Protocol Version Date 10/01/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 10/13/08 – Feasibility



- Informed Consent Document for Protocol Version Date 10/13/08 - Randomized Study

#### **COG-AREN0321**

#### **\*\*Immediate Suspension of Accrual of Patients to the Regimen UH-1 and Window Therapy Arms - Effective October 28, 2008\***

Amendment Review (AR): Immediate Suspension of Accrual by COG - Effective October 28, 2008

Documents Posted:

- 11/03/08: CIRB Acknowledgement of Immediate Suspension of Accrual Letter
- 10/28/08: COG Safety Advisory Memo

#### **COG-D9902**

Amendment Review (AR): Amendment #10 (Protocol Version Date 07/24/08)

Documents Posted:

- CIRB Application (Protocol Version Date 07/24/08)
- 10/22/08: CIRB Approval Letter (Protocol Version Date 07/24/08)
- 07/24/08: COG Change Memo (Protocol Version Date 07/24/08)
- Protocol Version Date 07/24/08
- Protocol Version Date 07/24/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 07/24/08

#### **ECOG-E2499**

Continuing Review (CR) Approval October 2008 Protocol Version Date 06/15/06

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/15/06)
- 11/07/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/15/06)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 06/15/06
- 10/20/08: Primary Reviewer 1 Comments

#### **ECOG-E5204**

Amendment Review (AR) Addendum 3 Approval Protocol Version Date 07/28/08

Documents Posted:

- 11/10/08: CIRB Acknowledgement of Receipt of Posting-Addendum 3
- 07/28/08 Change Memo (Protocol Version Date 07/28/08)
- CIRB Application (Protocol Version Date 07/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/28/08)
- 09/05/08: CIRB Addendum 3 Approval Letter (Protocol Version Date 07/28/08)
- Protocol Version Date 07/28/08
- Informed Consent Document for Protocol Version Date 07/28/08 [Add3]
- 09/05/08: Primary Reviewer 1 Comments



- 09/05/08: Minutes - Addendum 3 Review

#### **GOG-0218**

Amendment Review (AR) Revision 4 Approval Protocol Version Date 08/05/08  
Documents Posted:

- 05/07/08: Change Memo (Protocol Version Date 05/07/08)
- CIRB Application (Protocol Version Date 05/07/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/07/08)
- 09/09/08: CIRB Revision 4 Approval Letter (Protocol Version Date 08/05/08)
- 08/05/08: GOG Response Letter (Protocol Version Date 08/05/08)
- 07/14/08: CIRB Approval Pending Modifications (Protocol Version Date 05/07/08)
- Protocol Version Date 08/05/08
- Protocol Version Date 08/05/08 (Highlighted)
- Protocol Version Date 05/06/08
- Appendix I
- Appendix II
- Appendix III
- Appendix IV
- Appendix V
- Appendix VI
- Appendix VIII
- Appendix VIII (Highlighted)
- Informed Consent Document for Protocol Version Date 08/05/08 [Rev4]
- 06/16/08: Minutes - Amendment Review

#### **NCCTG-N0574**

Amendment Review (AR) Addendum 3 Approval Protocol Version Date 08/06/08  
Documents Posted:

- Change Memo (Protocol Version Date 08/06/08)
- CIRB Application (Protocol Version Date 08/06/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/06/08)
- 10/06/08: CIRB Addendum 3 Approval Letter (Protocol Version 08/06/08)
- Protocol Version Date 08/06/08 [Add3]
- Informed Consent Document for Protocol Version Date 08/06/08 [Per Add3]
- 10/03/08: Primary Reviewer 1 Comments

#### **NCCTG-N0574**

Continuing Review (CR) October 2008 Approval Protocol Version Date 08/06/08  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/06/08)
- 10/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/08)



- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 08/06/08
- Informed Consent Document for Protocol Version Date 08/06/08 [CR Oct08]
- 10/20/08: Primary Reviewer 1 Comments
- 04/08/08: DMC AE report
- April 2008 - Study Summary

#### **RTOG-0320**

Amendment Review (AR) Amendment 6 Approval Protocol Version Date 10/15/08  
Documents Posted:

- 10/15/08: Change Memo (Protocol Version Date 10/15/08)
- CIRB Application (Protocol Version Date 10/15/08)
- Summary of CIRB Application Revisions (Protocol Version Date 10/15/08)
- 10/23/08: CIRB Amendment 6 Approval (Protocol Version Date 10/15/08)
- CAEPR Version 2.1 (09/18/08)
- Protocol Version Date 10/15/08
- Protocol Version Date 10/15/08 (Highlighted)
- Informed Consent Document for Protocol Version Date 10/15/08 [Am6]

#### **RTOG-0521**

Continuing Review (CR) October 2008 Approval Protocol Version Date 05/15/08  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/15/08)
- 11/06/08: CIRB Continuing Review Approval Letter (Protocol version Date 05/15/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 05/15/08
- Informed Consent Document for Protocol Version Date 05/15/08 [CR08]
- Informed Consent Document (Tissue) for Protocol Version Date 05/15/08 [CR08]
- 10/20/08: Primary Reviewer 1 Comments
- 10/20/08: Primary Reviewer 2 Comments
- June 2008 - Study Summary
- 01/11/08: DMC Minutes

### **Serious Adverse Events**

**Study: ACOSOG Z1031**

**SAE Posted: 1351240, 1351240 FU3, 1726306 FU1, 1726306 FU2, 1726306 FU3**

**Study: CALGB 30607**

**SAE Posted: 1010206 FU1**



**Study: CALGB 40502**  
**SAE Posted: 1653936 FU1, 265261, 265652**

**Study: CALGB 40503**  
**SAE Posted: 1653936 FU1, 265261, 265652**

**Study: CALGB 80303**  
**SAE Posted: 1653936 FU1, 265261, 265652**

**Study: CALGB 90206**  
**SAE Posted: 1653936 FU1, 265261, 265652**

**Study: CALGB 90401**  
**SAE Posted: 1653936 FU1, 265261, 265652**

**Study: CALGB SWOG C80405**  
**SAE Posted: 07-02-12741, 08-02-13884 FU1, 08-02-14677 FU2, 265652, 265261**

**Study: ECOG E1105**  
**SAE Posted: 265652, 265261**

**Study: ECOG E1305**  
**SAE Posted: 265652, 265261**

**Study: ECOG E1505**  
**SAE Posted: 265652, 265261**

**Study: ECOG E1A05**  
**SAE Posted: 1940429 FU1**

**Study: ECOG E1A06**  
**SAE Posted: 1940429 FU1**

**Study: ECOG E2100**  
**SAE Posted: 265652, 265261**

**Study: GOG 0213**  
**SAE Posted: 260365 FU1, 263899 FU1**

**Study: GOG 0218**  
**SAE Posted: 260365 FU1, 263899 FU1**

**Study: NCCTG N0147**  
**SAE Posted: 07-02-12741**

**Study: NSABP B-34**



SAE Posted: 200816556 SU 84 FU1, 200822387 SU88 FU1, 200825602 FU1 SU 94, 200828478 SU 95

Study: RTOG 0320  
SAE Posted: 2008SP006508 FU1

Study: RTOG 0436  
SAE Posted: 08-02-14882

Study: RTOG 0522  
SAE Posted: 08-02-14481 FU1, 08-02-14660, 08-02-14660 FU1, 08-02-14882

Study: SWOG S0600  
SAE Posted: 08-02-13884 FU1, 08-02-14677 FU2

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## Corrections to Previous Study Activity Updates

### ECOG-E2805

Amendment Review (AR) Addendum 4 Approval Protocol Version Date 03/11/08  
Documents Posted:

10/29/08: CIRB Acknowledgement of Clarification to Addendum 4

10/01/08: ECOG Change Memo Clarification [Add4]

Correction:

**Clarification:** Item number 76 of the Addendum #4 change memo should read as follows: Appendix I (page 7): In the “How long will I be in the study?” section, the second sentence in the first paragraph was revised to read: “You will continue to be followed for an additional 9 years for a total study duration of 10 years to look at the long-term effects of the study.” In the same section, the following paragraph was deleted: “We would like to keep track of your medical condition for 10 years to look at the long-term effects of the study.” The sentence beginning “If you experience any problems...” was moved below the sentence beginning “Your study doctor...” The following bullet was added under “Likely”, “Decrease in the amount of your thyroid hormone (which may cause fatigue, cold sensitivity, leg swelling, or other symptoms).”

**NOTE:** On page 8 of Appendix I, please be aware that the following side effect was inadvertently listed twice:  
“Elevated liver laboratory tests which could indicate injury to the liver.” This duplication will be corrected in a future addendum.



### **GOG-0218**

Amendment Review (AR) Revision 4 Approval Protocol Version Date 08/05/08  
Documents Posted:

11/04/08: CIRB Revision 4 Approval Letter-Corrected Version

11/04/08: CIRB Revision 4 Outcome Letter Correction-Letter Dated 09/09/08

Correction:

The GOG-0218 Revision #4 approval letter, dated September 9, 2008 contains an error. The letter stated that **CIRB approval for this protocol will expire on June 15, 2008**. The letter should have stated that **CIRB approval for this protocol will expire on November 25, 2008**.

### **NCCTG-N0147**

**Study Accrual Suspension Notice** (Amendment Tab)

Documents Posted:

11/06/08: CIRB Acknowledgement of Receipt-Revised Physician Letter

10/30/08: NCCTG Clarification to the October 24, 2008 Physician Letter

10/21/08: Additional Material Memo

10/21/08: NCCTG Site Payments

Correction:

The purpose of these memoranda is to provide clarification to the October 24, 2008 Dear Doctor letter posted on CTSU.

### **NCCTG-N0723**

Initial Review (IR) Approval 2008 Protocol Version Date 03/13/08

Documents Posted:

10/23/08: CIRB Correction to Table of Initial Review (Protocol Version Date 03/13/08)

Correction:

The NCCTG N0723 Table of Initial Review letter dated May 20, 2008 contains an error. The protocol version date cited in the letter is incorrect. CIRB Operations Staff noted a discrepancy between the protocol version date listed in the application (PVD 3/25/2008) and in the protocol (PVD 3/13/2008) and have confirmed with study staff the date listed in the application was an error. The May 20, 2008 letter has been revised to include the correct protocol version date (PVD 3/13/2008)



#### **NSABP-B-43**

**\*\* Study to be Activated November 10, 2008**

Activation Date changed from November 13, 2008 to November 10, 2008

Documents Posted:

10/17/08: Trial Initiation of NSABP B-43

Correction:

Date of activation changed from November 13 to November 10, 2008.

#### **RTOG-0617**

Protocol Title Changed on NCI/CIRB Website to reflect Amendment 1

Documents Posted:

A Randomized Phase III Comparison of Standard-Dose (60 Gy) versus High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- **Cetuximab** in Patients with Stage IIIa/IIIb Non-Small Cell Lung Cancer

11/10/08: CIRB Correction-Amendment 2 Approval Letter Dated 09/17/08

11/07/08: CIRB Amendment 2 Approval Letter

Correction:

The following phrase: '**+/- Cetuximab**' (added and approved in amendment 1) was inadvertently not updated in the title in various locations, including the website.

#### **SWOG-S0600**

Amendment Review (AR) Revision #1 Approval Protocol Version Date 04/10/08

Documents Posted:

11/03/08: CIRB Approval of SWOG S0600 Revision #1

11/03/08: Correction to SWOG S0600 Revision #1 Outcome Letter Dated 06/05/08

Correction:

The SWOG S0600 Revision #1 approval letter dated 06/05/08 contains an error. It stated Revision # 1 **did not** involve changes to the informed consent form. The letter should read Revision # 1 **did** involve changes to the informed consent form.

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).