



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

**January 15, 2009**

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:**

### **ACOSOG-Z1041 A1**

Amendment Review (AR): Participant Recruitment Material Approval  
Documents Posted:

- 01/02/09: CIRB Approval Letter for Patient Brochure
- 12/16/08: CIRB Approval Pending Modification of the Recruitment Materials
- 12/18/08: ACOSOG Response to CIRB
- Patient Recruitment Brochure
- 11/12/08: Primary Reviewer 2 Comments
- 11/12/08: Minutes - Patient Recruitment Material-Patient Brochure

### **COG-AALL03B1**

Amendment Review (AR): Amendment #6 (Protocol Version Date 11/14/08)  
Documents Posted:

- CIRB Application (Protocol Version Date 11/14/08)
- 12/29/08: CIRB Acknowledgement of COG AALL03B1 Amendment #6
- 12/19/08: CIRB Approval of Amendment #6 Letter (Protocol Version Date 11/14/08)
- 11/14/08: COG Change Memo (Protocol Version Date 11/14/08)
- Protocol Version Date 11/14/08
- Protocol Version Date 11/14/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 11/14/08 - ADDITIONAL BONE MARROW
- Informed Consent Document for Protocol Version Date 11/14/08 – STUDY ENTRY AND SHIPMENT OF SAMPLES

### **COG-AALL0433**

Amendment Review (AR): **Amendment #1 - Study Reactivation**  
Documents Posted:

- CIRB Application (Protocol Version Date 11/12/08)
- CIRB Application (Protocol Version Date 08/20/08)
- 01/12/09: CIRB Acknowledgement of Amendment #1 - Reopening to Accrual Memo
- 01/12/09: COG Change Memo (Protocol Version Date 11/12/08)
- 12/22/08: CIRB Amendment #1 Approval Letter (Protocol Version Date 11/12/08)
- 11/12/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/20/08)



- 11/06/08: CIRB Approval Pending Modification Letter (Protocol Version Date 08/20/08)
- Protocol Version Date 11/12/08
- Protocol Version Date 11/12/08 - Highlighted Changes
- Protocol Version Date 08/20/08
- Protocol Version Date 08/20/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 11/12/08
- 10/16/08: Primary Reviewer 1 Comments
- 10/16/08: Minutes - Amendment Review

Amendment Review (AR): **NCI Information Sheet Re Use of Banked Tissue for Research**

Documents Posted:

- 01/05/09: CIRB Acknowledgement-Update NCI Information Sheet Re Use of Banked Tissue for Research Memo
- 12/12/08: COG Update-NCI information sheet re use of banked tissue for research Memo

#### **COG-AALL0434**

Amendment Review (AR): Amendment #3 (Protocol Version Date 10/31/08)

Documents Posted:

- CIRB Application (Protocol Version Date 10/31/08)
- 12/31/08: CIRB Acknowledgement of COG AALL0434 Amendment #3 Memo
- 12/22/08: CIRB Approval Letter (Protocol Version Date 10/31/08)
- 10/31/08: COG Change Memo (Protocol Version Date 10/31/08)
- Protocol Version Date 10/31/08
- Protocol Version Date 10/31/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 10/31/08: Part I - Induction Therapy
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - Low Risk
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - Intermediate Risk
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - High Risk
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - Induction Failure



#### **COG-AALL06N1**

Continuing Review (CR): Continuing Review June 2008

Documents Posted:

- 06/12/08: Primary Reviewer 1 Comments
- 06/12/08: Minutes - Continuing Review

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

#### **COG-AALL07P4**

Amendment Review (AR): Activation Amendment (Protocol Version

Date 05/21/08)

Documents Posted:

- 06/05/08: Primary Reviewer 1 Comments
- 06/05/08: Minutes - Amendment Review

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

#### **COG-AALL0431**

Amendment Review (AR): **Enrollment Interruptions Due to the Temporary Closure of ACCL05C1 (Protocol Version Date 01/24/08)**

Documents Posted:

- 01/14/09: CIRB Acknowledgement of Enrollment Interruptions -Temporary Closure of ACCL05C1
- 10/31/08: COG Enrollment Interruptions Memo

#### **COG-ADVL06B1**

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/29/07)
- 01/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/29/07)
- 12/30/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/29/07)
- 12/12/08: CIRB Approval Pending Modification Letter (Protocol Version Date 11/29/07)
- 10/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/29/07
- Protocol Version Date 11/29/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 11/29/07
- 11/13/08: Primary Reviewer 1 Comments



- 11/13/08: Minutes - Continuing Review
- 08/25/08: Study Progress Report

#### **COG-AEWS07B1**

Amendment Review (AR): **NCI Information Sheet Re Use of Banked Tissue for Research**

Documents Posted:

- 01/02/09: CIRB Acknowledgement-Update NCI Information Sheet Re Use of Banked Tissue for Research Memo
- 12/12/08: COG Update-NCI information sheet re use of banked tissue for research Memo

#### **COG-AHOD04B1**

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/30/07)
- 12/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 04/30/07)
- 12/17/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 04/30/07)
- 12/12/08: CIRB Approval Pending Modification Letter (Protocol Version Date 04/30/07)
- 10/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 04/30/07
- Protocol Version Date 04/30/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 04/30/07)
- 08/25/08: Study Progress Report

#### **COG-AHOD0431**

Amendment Review (AR): **Temporary Closure to Accrual Effective December 4, 2008**

Documents Posted:

- 01/02/09: CIRB Acknowledgement-Temporary Closure Clarifications Memo
- 12/24/08: COG Temporary Closure Clarifications Memo

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



#### **COG-AHOD0521**

Continuing Review (CR): Continuing Review November 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/01/07)
- 12/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/01/07)
- 12/17/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/01/07)
- 12/12/08: CIRB Approval Pending Modification Letter (Protocol Version Date 05/01/07)
- 10/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/01/07
- Protocol Version Date 05/01/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 05/01/07
- 04/11/08: DSMC Report
- 08/25/08: Study Progress Report

#### **COG-AOST0331**

Amendment Review (AR): [NCI Information Sheet Re Use of Banked Tissue for Research](#)

Documents Posted:

- 01/02/09: CIRB Acknowledgement-Update NCI Information Sheet Re Use of Banked Tissue for Research Memo
- 12/12/08: COG Update-NCI information sheet re use of banked tissue for research Memo

Continuing Review (CR): Continuing Review May 2008

Documents Posted:

- 06/05/08: Primary Reviewer 1 Comments
- 06/05/08: Minutes - Continuing Review

**[Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.](#)**

#### **COG-AOST06P1**

Amendment Review (AR): [NCI Information Sheet Re Use of Banked Tissue for Research](#)

Documents Posted:

- 01/02/09: CIRB Acknowledgement-Update NCI Information Sheet Re Use of Banked Tissue for Research Memo



- 12/12/08: COG Update-NCI information sheet re use of banked tissue for research Memo

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**  
Documents Posted:

- 12/29/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

#### **COG-ASCT0431**

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

- 12/30/08: Correction to ASCT0431 Posted Informed Consent Document

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

#### **COG-D9902**

Amendment Review (AR): **NCI Information Sheet Re Use of Banked Tissue for Research**  
Documents Posted:

- 01/02/09: CIRB Acknowledgement-Update NCI Information Sheet Re Use of Banked Tissue for Research Memo
- 12/12/08: COG Update-NCI information sheet re use of banked tissue for research Memo

#### **ECOG-E1A05**

Continuing Review (CR) Approval January 2009  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/25/08)
- 01/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/25/08)
- 11/07/08: Continuing Review Reminder Notice (Protocol Version Date 04/25/08)
- Protocol Version Date 04/25/08
- Informed Consent Document for Protocol Version Date 04/25/08 [CR Jan09]
- 01/09/09: Primary Reviewer 1 Comments
- November 2008 - Study Summary
- 10/29/08 & 11/04/08 ECOG DMC Recommendations



### **ECOG-E1305**

Amendment Review (AR) Addendum 2 Approval (Protocol Version Date 11/19/08)  
Documents Posted:

- 11/19/08: Change Memo (Protocol Version Date 11/19/08)
- CIRB Application (Protocol Version Date 11/19/08)
- Summary of CIRB Application Revisions (Protocol Version Date 11/19/08)
- 12/30/08: CIRB Acknowledgement-Addendum 2 (Activation Date: 01/21/09)
- 12/03/08: CIRB Addendum 2 Approval Letter (Protocol Version date 11/19/08)
- Protocol Version Date 11/19/08
- Informed Consent Document for Protocol Version Date 11/19/08 [Add2]

### **ECOG-E5202**

Amendment Review (AR) Update 4 Approval (Protocol Version Date 12/19/08)  
Documents Posted:

- 12/19/08: Change Memo (Protocol Version Date 12/19/08)
- CIRB Application (Protocol Version Date 12/19/08)
- Summary of CIRB Application Revisions (Protocol Version Date 12/19/08)
- 01/12/09: CIRB Update 4 Approval Letter (Protocol Version Date 12/19/08)
- Protocol Version Date 12/19/08
- Informed Consent Document for Protocol Version Date 12/19/08 [per Up4]

### **NCCTG-N0723**

Amendment Review (AR): Addendum #1 (Protocol Version Date 10/28/08)  
Documents Posted:

- Change Memo (Protocol Version Date 10/28/08)
- CIRB Application (Protocol Version Date 10/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 10/28/08)
- 01/05/09: CIRB Acknowledgement of Addendum 1 (Activation Date 01/06/09)
- 12/18/08: CIRB Addendum 1 Approval Letter (Protocol Version Date 10/28/08)
- Protocol Version Date 10/28/08
- Informed Consent Document for Protocol Version Date 10/28/08 [Per Add1]
- Informed Consent Document for Protocol Version Date 11/19/08 [Add2]



### **NCIC CTG-MA.27**

Continuing Review (CR) Approval January 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/07/08)
- 01/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/07/08)
- 12/03/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 04/07/08
- 01/09/09: Primary Reviewer 1 Comments
- AE Report
- Fall 2008 - DSMC Report
- Spring 2008 - Study Summary

### **SWOG-S0521**

Amendment Review (AR): Revision #2 (Protocol Version Date 10/05/08)

Documents Posted:

- 10/21/08: Change Memo (Protocol Version Date 10/05/08)
- 11/19/08: CIRB Revision 2 Approval Letter (Protocol Version Date 10/05/08)
- Protocol Version Date 10/05/08
- 11/12/08: Primary Reviewer 1 Comments
- 11/12/08: Minutes - Revision 2
- Informed Consent Document for Protocol Version Date 10/05/08 [Rev2]
- Informed Consent Document (Notes for Local institutions) for Protocol Version Date 10/05/08

## **Serious Adverse Events**

**Study: CALGB 30607**  
**SAE Posted: 1779400 FU1**

**Study: CALGB 80203**  
**SAE Posted: 08-02-14677 FU2**

**Study: CALGB-SWOG C80405**  
**SAE Posted: 08-02-14973**

**Study: ECOG E2603**  
**SAE Posted: 1274544 FU1**

**Study: ECOG E2805**



**SAE Posted: 1274544 FU1, 1779400 FU1**

**Study: NCCTG N0147  
SAE Posted: 08-02-14973**

**Study: NSABP B-34  
SAE Posted: 200715313 SU65 FU2, 200715313 SU65 FU3, 200812671 SU73  
FU1, 200820008 SU85 FU2, 200825602 SU 94, 200829546 SU97 FU1, FR-2007-  
041732 SU61 FU1**

**Study: NSABP B-38  
SAE Posted: ES200808004816, FR200806004114 FU1, GBT040801564,  
US200708005949 FU1**

**Study: NSABP B-40  
SAE Posted: 1226348 FU1, 1466045 FU1, 263520 FU2, 263914 FU3, 263914  
FU4, 265033 FU1, 265652 FU2, 265846 FU1, 265846 FU2, 266802 FU1, 267119,  
267119 FU1, 268517, ES200808004816, FR200806004114 FU1, GBT040801564**

**Study: NSABP C-08  
SAE Posted: 1226348 FU1, 1466045 FU1, 231325 FU5, 263520 FU2, 263914  
FU3, 263914 FU4, 265033 FU1, 265652 FU2, 265846 FU1, 265846 FU2, 266802  
FU1, 267119, 267119 FU1, 268517**

**Study: RTOG 0320  
SAE Posted: 2007SP018230 FU9, 2008SP010385 FU1, 265261, 265652**

**Study: RTOG 0436  
SAE Posted: 08-02-14028 FU1, 07-02-12741, 08-02-14475 FU1, 08-02-14619,  
08-02-14677, 08-02-14677 FU2, 08-02-14690 FU1, 08-02-14699, 08-02-14699  
FU1, 08-02-14882 FU1, 08-02-15043, 08-02-15200**

**Study: RTOG 0522  
SAE Posted: 07-02-12741, 07-02-13172 FU1, 08-02-14028 FU1, 08-02-14426  
FU1, 08-02-14475 FU1, 08-02-14619, 08-02-14677, 08-02-14677 Fu2, 08-02-  
14690 FU1, 08-02-14699, 08-02-14699 FU1, 08-02-14882 FU1, 08-02-15043, 08-  
02-15200**

**Study: RTOG 0525  
SAE Posted: 2007SP018230 FU9**

**Study: SWOG S0600  
SAE Posted: 08-02-14426 FU1, 08-02-14973**



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

### **GOG-0218**

Continuing Review Approval September 2008

Documents Posted:

CIRB Continuing Review Application-(Protocol Version Date 08/05/08)

01/07/09: CIRB Acknowledgement of Revised CIRB Application (Protocol Version date 08/05/08)

Correction:

Revised CIRB application for September 2008 Continuing Review and the expedited outcome letter with Chair's signature added to web site.

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).