



## NCI Central IRB Study Activity Update October 15, 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-AALL0331

#### **\*\* Study Reactivation by COG - Effective September 29, 2008\*\***

Amendment Review (AR): Approval Amendment #2C - Study Reactivation  
(Protocol Version Date 09/04/08)

Documents Posted:

- CIRB Application (Protocol Version Date 09/04/08)
- CIRB Application (Protocol Version Date 07/14/08)
- 09/29/08: Amendment #2C - Study Reactivation Memo (Protocol Version Date 09/04/08)
- 09/17/08: CIRB Approval Letter (Protocol Version Date 09/04/08)
- 09/04/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 07/14/08)
- 08/27/08: CIRB Approval Pending Modification Letter (Protocol Version Date 07/14/08)
- 07/15/08: Change Letter (Protocol Version Date 07/14/08)
- Protocol Version Date 09/04/08
- Protocol Version Date 09/04/08 - Highlighted Changes
- Protocol Version Date 07/14/08
- Protocol Version Date 07/14/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 09/04/08 - Induction Therapy
- Informed Consent Document for Protocol Version Date 09/04/08 - Standard Risk: High
- Informed Consent Document for Protocol Version Date 09/04/08 - Standard Risk: Average
- Informed Consent Document for Protocol Version Date 09/04/08 - Standard Risk: Low
- Informed Consent Document for Protocol Version Date 09/04/08 - Treatment Changes

### COG-AALL0631

Amendment Review (AR): CIRB Acknowledgment of AALL0631 Protocol and Sample Informed Consent Errors (Protocol Version Date 11/02/07)

Documents Posted:

- 10/03/08: CIRB Acknowledgment of Protocol and Sample Informed Consent Errors
- 09/12/08: COG Errors Memo (Protocol Version Date 11/02/07)



### **COG-AAML06P1**

**\*\*Temporarily Closed to Accrual by COG - Effective September 26, 2008\*\***

Amendment Review (AR): Acknowledgement of Temporary Closure to Accrual (09/26/08)

Documents Posted:

- 09/29/08: CIRB Acknowledgement of Temporary Closure to Accrual
- 09/26/08: AAML06P1 Temporary Closure to Accrual

**\*\*Study Reactivation by COG - Effective October 10, 2008\*\***

Amendment Review (AR): CIRB Acknowledgement of AAML06P1 Study Reactivation

Documents Posted:

- 10/13/08: CIRB Acknowledgement of COG AAML06P1 Study Reactivation
- 10/10/08: COG Reactivation Memo

### **COG-ALTE05N1**

Continuing Review (CR): September 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/12/08)
- 09/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/12/08)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/12/08
- Informed Consent Document for Protocol Version Date 02/12/08

### **COG-AREN0533**

Amendment Review (AR): CIRB Acknowledgment of AREN0533 Clarifications on Discrepancy between the Protocol and the Youth Information Summaries / Informed Consent Document (Protocol Version Date 06/17/08)

Documents Posted:

- 10/03/08: CIRB Acknowledgment of Clarifications on Discrepancy Letter (Protocol Version Date 06/17/08)
- 09/19/08: COG Clarifications Memo (Protocol Version Date 06/17/08)

Continuing Review (CR): September 2008 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/14/06)
- 09/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/17/08)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/17/08



- Informed Consent Document for Protocol Version Date 06/17/08
- 04/11/08: DSMC Report
- 02/04/08: Study Progress Report

#### **COG-ASCT0631**

**\*\*Temporary Closure to Accrual by COG - Effective October 10, 2008\*\***

Amendment Review (AR): CIRB Acknowledgment of ASCT0631 Temporary Closure to Accrual  
Documents Posted:

- 10/13/08: CIRB Acknowledgement of COG ASCT0631 Temporary Closure to Accrual
- 10/10/08: COG Temporary Suspension of Enrollment to ASCT0631

#### **ECOG-E1Y03**

**\*\*Closed to Accrual - Effective October 15, 2008 at 5:00 pm EST\*\***

Documents Posted:

- 10/14/08: CIRB Acknowledgement of Receipt-Memo of Closure to New Accrual
- 09/30/08: ECOG Broadcast Notification of Closure to Accrual

#### **ECOG-E1105**

Amendment Review (AR): Addendum 3 (Protocol Version Date 06/12/08)  
Documents Posted:

- 06/12/08: Change Memo
- CIRB Application (Protocol Version Date 06/12/08)
- 09/02/08: CIRB Addendum 3 Approval Letter (Protocol Version Date 06/12/08)
- Protocol Version Date 06/12/08 [Per Add3]
- Summary of CIRB Application Revisions (Protocol Version Date 06/12/08)
- Informed Consent Document for Protocol Version Date 06/12/08 [Per Add3]
- 07/21/08: Primary Reviewer 1 Comments
- 07/21/08: Minutes - Addendum 3 Review

#### **GOG-0218**

Continuing Review (CR): September 2008 Approval  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/05/08)
- 09/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 07/13/07)
- 07/14/08: Continuing Review Reminder Notice



- Protocol Version Date 07/13/07
- Appendix I
- Appendix II
- Appendix III
- Appendix IV
- Appendix V
- Appendix VI
- Appendix VII
- Appendix VIII
- Informed Consent Document for Protocol Version Date 07/13/07 [Per Sep08 CR]
- 09/15/08: Primary Reviewer 1 Comments
- 01/26/08: DSMB Report

#### **NSABP-B-40**

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

- CIRB Continuing Review Application (Protocol Version Date 02/15/08)
- 10/06/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/15/08)
- 09/05/08: Cover Memo
- 08/07/08: Continuing Review Reminder Notice (Protocol Version Date 02/15/08)
- Protocol Version Date 02/15/08 [Per Oct08 CR]
- Informed Consent Document for Protocol Version Date 02/15/08 [Per Oct08 CR]
- 10/03/08: Primary Reviewer 1 Comments
- Study Summary

#### **RTOG-0617**

Amendment Review (AR): Amendment 1 (Protocol Version Date 06/18/08)  
Documents Posted:

- 06/18/08: Change Memo
- CIRB Application (Protocol Version Date 06/18/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/18/08)
- 10/07/08: Group Broadcast-Activation of Amendment 1
- 08/20/08: CIRB Amendment 1 Approval Letter (Protocol Version Date 06/18/08)
- Protocol Version Date 06/18/08
- Protocol Version Date 06/18/08 (Highlighted)
- Informed Consent Document for Protocol Version Date 06/18/08 [Per Am1]
- 08/18/08: Minutes - Amendment 1 Review



## Serious Adverse Events

**Study: COG ADVL0221**

**SAE Posted: GB-JNJFOC-20071109894 FU4, US-JNJFOC-20070902093 FU2, US-JNJFOC-20080100956 FU2, US-JNJFOC-20080206633, US-JNJFOC-20070902657 FU3, IE-JNJFOC-20080302875, US-JNJFOC-20071007918 FU4, US-JNJFOC-20061203739 FU3, US-JNJFOC-20080400179 FU2, AT-JNJFOC-20080600925, AT-JNJFOC-20080600925 FU1, AT-JNJFOC-20080600925 FU2, AT-JNJFOC-20080600925 FU3, DE-JNJFOC-20080407700, FR-JNJFOC-20080505419, IE-JNJFOC-20080302875 FU2, SE-JNJFOC-20080501092 FU2, SE-JNJFOC-20080501092 FU3, US-JNJFOC-20070902657 FU4, US-JNJFOC-20080206633 FU3, US-JNJFOC-20080400179 FU3, US-JNJFOC-20080403865 FU1, US-JNJFOC-20080502379 FU1, US-JNJFOC-20080502379 FU2, US-JNJFOC-20080701515, ZA-JNJFOC-20080602469, ZA-JNJFOC-20080602469 FU1.**

**Study: COG ADVL0525**

**SAE Posted: AR200806005488, BR200807000959, TW200804007295 FU2.**

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## Corrections to Previous Study Activity Updates

### ECOG-E2902

Title of Study Incomplete

Correction: Updated Title of Study on NCI CIRB web to include the last phrase: ".....or Patients over Age 60 in the First Remission" per Addendum 4

### ECOG-PACCT-1

Continuing Review (CR) June 2008 Approval  
Documents Posted:

06/16/08: Minutes - Continuing Review

Correction: Error in voting box corrected.

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).