



## NCI Central IRB Study Activity Update

May 31, 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:**

### **CALGB-40502**

Amendment Review (AR): [CIRB Acknowledgement of Updated Ixabepilone Investigator Brochure Vers 10 dated 03/27/09](#)

Documents Posted:

- 05/21/09: CIRB Acknowledgement of Receipt-Updated Ixabepilone IB Vers 10 dated 03/27/09

### **CALGB-70301**

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/09/08)
- 05/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/09/08)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 04/09/08
- Informed Consent Document for Protocol Version Date 04/09/08 [CR09]
- Study Summary - December 2008

### **CALGB-90401**

Amendment Review (AR): Update 4 (Protocol Version Date 03/09/09)

Documents Posted:

- 04/15/09: Change Memo (Protocol Version Date 03/09/09)
- 05/01/09: CIRB Update 4 Approval Letter (Protocol Version Date 03/09/09)
- Protocol Version Date 03/09/09
- Informed Consent Document for Protocol Version Date 03/09/09

### **COG-AALL03N1**

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- 04/02/09: 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-AAML07P1

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/22/09)
- 05/26/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/22/09)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 01/22/09
- Informed Consent Document for Protocol Version Date 01/22/09 - ARM A
- Informed Consent Document for Protocol Version Date 01/22/09 - ARM B
- 05/14/09: Primary Reviewer 1 Comments
- Spring 2009 Study Progress Report
- 10/02/08: DSMC Report
- 08/25/08: Study Progress Report

### COG-ACNS0232

**\*\*Closed to Accrual by COG - Effective May 18, 2009\*\***

Amendment Review (AR): [Acknowledgement of ACNS0232 Study Closure \(05/18/09\)](#)

Documents Posted:

- 05/19/09: CIRB Acknowledgement of COG ACNS0232 Study Closure
- 05/18/09: COG Memo - Closure of ACNS0232
- Informed Consent Document for Protocol Version Date 06/09/08

### COG-ADVL0221

**\*\*Temporarily Closed to Accrual by COG - Effective May 13, 2009\*\***

Amendment Review (AR): [Acknowledgement of ADVL0221 Temporary Closure to Accrual \(05/13/09\)](#)

Documents Posted:

- 05/19/09: CIRB Acknowledgement of COG ADVL0221 Temporary Study Closure Memo
- 05/13/09: COG Memo - Temporary Closure of ADVL0221

### COG-AGCT0521

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- 04/02/09: 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-AHOD0431**

Amendment Review (AR): **Review of AHOD0431 Family/Patient Letter (Dated 12/15/08) regarding Temporary Closure to Accrual**

Documents Posted:

- 05/18/09: CIRB Approval of the Family/Patient Letter for AHOD0431
- 04/22/09: COG Response to PedCIRB APM Outcome Family/Patient Study Suspension Letter
- 01/21/09: CIRB Approval Pending Modification of the AHOD0431 Patient/Family Letter
- 12/15/08: Patient/Family Letter
- 01/08/09: Primary Reviewer 1 Comments - Patient/Family Letter
- 01/08/09: Minutes - Recruitment Material - Patient/Family Letter

**COG-ALTE07C1**

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/28/08)
- 05/26/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/28/08)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 07/28/08
- Informed Consent Document for Protocol Version Date 07/28/08
- 05/14/09: Primary Reviewer 1 Comments
- Spring 2009 Study Progress Report

**COG-ANBL00P3**

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- 04/02/09: 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-ARAR0331**

Amendment Review (AR): Amendment #1 (Protocol Version Date 04/14/09)

Documents Posted:



- 05/05/09: CIRB Approval of COG ARAR0331 Amendment #1 (Protocol Version Date 04/14/09)

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

#### **COG-AREN0321**

Amendment Review (AR): **Review of AREN0321 Family/Patient Letter (Dated 11/10/08) regarding Treatment Regimens UH-1 and UH-2**

Documents Posted:

- 05/18/09: CIRB Approval of the Family/Patient Letter for AREN0321
- 04/22/09: COG Response to Ped CIRB APM of the Recruitment Materials for AREN0321 Outcome Family/Patient Study
- 12/12/08: CIRB Approval Pending Modification of the Recruitment Materials for AREN0321
- 11/10/08: COG Dear Parents Letter
- 11/13/08: Minutes - Review of AREN0321 Family/Patient Letter

#### **COG-ARET0331**

Amendment Review (AR): **Review of ARET0331 Family/Patient Letter (Dated 1/26/09) regarding Suspension of Enrollment and Treatment**

Documents Posted:

- 02/06/09: CIRB Approval of the ARET0331 Family/Patient Study Suspension Letter
- 01/26/09: COG Response to PedCIRB APM Outcome Family/Patient Study Suspension Letter
- 01/26/09: Patient/Family Letter - Revised
- 01/26/09: Patient/Family Letter - Revised (Tracked Changes)
- 01/21/09: CIRB Approval Pending Modification of the ARET0331 Patient/Family Letter
- 12/29/08: Patient/Family Letter
- 01/08/09: Minutes - Recruitment Material - Patient/Family Letter

#### **COG-ARET0332**

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/21/08)
- 05/14/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/21/08)



- 05/05/09: COG Response to Disapproval of the Group Response Letter (Protocol Version Date 11/21/08)
- 05/01/09: CIRB Disapproval of the Group Response Letter (Protocol Version Date 11/21/08)
- 04/02/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/21/08)
- 03/31/09: CIRB Approval Pending Modification Letter (Protocol Version Date 11/21/08)
- 02/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/21/08
- Informed Consent Document for Protocol Version Date 11/21/08 - Observation Arm
- Informed Consent Document for Protocol Version Date 11/21/08 - Chemotherapy Arm
- 05/14/09: Primary Reviewer 1 Comments
- 03/12/09: Primary Reviewer 1 Comments
- 04/21/09: Minutes - Group Response to Continuing Review
- 03/12/09: Minutes - Continuing Review
- Spring 2009 Study Progress Report
- 04/03/09: DSMC Report

#### **ECOG-E1A00**

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/30/07)
- 05/20/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/30/07)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 05/30/07
- Informed Consent Document for Protocol Version Date 05/30/07
- 05/01/08: Journal of Clinical Oncology Report (Rajkumar)
- 01/30/06: Journal of Clinical Oncology Report (Rajkumar)
- 11/04/03: DMC Report
- Study Summary - November 2004

#### **ECOG E1A05**

Amendment Review (AR): Addendum #3 (Protocol Version Date 02/20/09)

Documents Posted:

- 02/20/09: Change Memo (Protocol Version Date 02/20/09)
- CIRB Application (Protocol Version Date 02/20/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/20/09)



- 04/13/09: CIRB Approval Letter Addendum 3 (Protocol Version Date 02/20/09)
- Protocol Version Date 02/20/09
- Informed Consent Document for Protocol Version Date 02/20/09 [ad3]
- 04/03/09: Primary Reviewer 1 Comments
- 04/03/09: Minutes - Addendum 3

#### **ECOG E1900**

Amendment Review (AR): Update #3 (Protocol Version Date 05/14/08)

Documents Posted:

- 05/14/08: Change Memo (Protocol Version Date 05/14/08)
- CIRB Application (Protocol Version Date 05/14/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/14/08)
- 07/21/08: CIRB Update 3 Approval Letter (Protocol Version Date 05/14/08)
- Protocol Version Date 05/14/08
- Informed Consent Document for Protocol Version Date 05/14/08 [Up3]

#### **ECOG E2805**

Amendment Review (AR): Addendum #6 (Protocol Version Date 05/04/09)

Documents Posted:

- 05/04/09: Change Memo (Protocol Version Date 05/04/09)
- 02/25/09: Change Memo (Protocol Version Date 02/25/09)
- CIRB Application (Protocol Version Date 02/25/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/25/09)
- 05/12/09: CIRB Approval Addendum 6 (Protocol Version Date 05/04/09)
- 04/21/09: CIRB Approval Pending Modifications Letter Addendum 6 (Protocol Version Date 02/25/09)
- Protocol Version Date 05/04/09
- Protocol Version Date 02/25/09
- Informed Consent Document for Protocol Version Date 05/04/09 [Ad6]
- 04/03/09: Primary Reviewer 1 Comments
- 04/03/09: Minutes - Addendum 6

#### **ECOG E5202**

Amendment Review (AR): CIRB Approval of Recruitment Materials

Documents Posted:

- 05/26/09: CIRB Approval Letter-Dear Participant Memo (dated 5/5/09)
- Letter to Participants of ECOG E5202



### **GOG-0218**

Amendment Review (AR): Update 04/13/09 (Protocol Version Date 02/27/09)

Documents Posted:

- 05/14/09: Change Memo (Protocol Version Date 02/27/09)
- 05/14/09: CIRB Approval Letter of April 13, 2009 Update (Protocol Version Date 02/27/09)
- Protocol Version Date 02/27/09 (Update 04/13/09)
- Informed Consent Document for Protocol Version Date 02/27/09 [Update 04/13/09]

### **NCCTG-N0147**

Amendment Review (AR): Addendum #10 (Protocol Version Date 04/21/09)

Documents Posted:

- 04/21/09: NCCTG Change Memo (Protocol Version Date 04/21/09)
- CIRB Application (Protocol Version Date 04/21/09)
- Summary of CIRB Application Revisions (Protocol Version Date 04/21/09)
- CIRB Application (Protocol Version Date 03/04/09)
- Summary of CIRB Application Revisions (Protocol Version Date 03/04/09)
- 04/27/09: CIRB Addendum 10 Approval Letter (Protocol Version Date 04/21/09)
- 04/20/09: CIRB Addendum 10 Approval Pending Modifications Letter (Protocol Version Date 03/04/09)
- Protocol Version Date 04/21/09
- Protocol Version Date 03/04/09
- Informed Consent Document for Protocol Version Date 04/21/09 [add10]
- 04/03/09: Primary Reviewer 1 Comments
- 04/03/09: Minutes - Addendum 10

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

Amendment Review (AR): Amendment #10 (Protocol Version Date 03/06/09)

Documents Posted:

- Change Memo (Protocol Version Date 03/06/09)
- CIRB Application (Protocol Version Date 03/06/09)
- Summary of CIRB Application Revisions (Protocol Version Date 03/06/09)
- 04/01/09: CIRB Approval Letter Amendment 10 (Protocol Version Date 03/06/09)
- Protocol Version Date 03/06/09 [Companion]

### **NSABP-B-34**



Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/19/07)
- 05/14/09: CIRB Approval Letter Continuing Review (Protocol Version Date 04/19/07)
- 05/08/09: NSABP Cover memo
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 04/19/07
- Informed Consent Document for Protocol Version 04/19/07
- 10/17/08: DMC Minutes
- Study Summary

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

Amendment Review (AR): **[CIRB Acknowledgement-Updated Capecitabine Investigator's Brochure](#)**

Documents Posted:

- 05/14/09: Acknowledgement of Receipt for Updated Capecitabine Investigator's Brochure

#### **SWOG-S0205**

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/21/07)
- 05/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/21/07)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 02/21/07
- Informed Consent Document for Protocol Version Date 02/21/07

#### **SWOG-S0221**

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/01/08)
- 05/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/01/08)
- 03/06/09: Continuing Review Reminder Notice
- Protocol Version Date 01/01/08



- Informed Consent Document for Protocol Version Date 01/01/08 [CR09]
- 05/07/09: Primary Reviewer 1 Comments
- 04/13/09: SAEs Attributed at Least Possibly Related to Treatment
- April 2009 - Study Summary
- 10/31/08: DSMC Minutes

### **SWOG-S0521**

Amendment Review (AR): Revision #3 (Protocol Version Date 03/06/09)

Documents Posted:

- 03/06/09: Change Memo (Protocol Version Date 03/06/09)
- CIRB Application (Protocol Version Date 03/06/09)
- Summary of CIRB Application Revisions (Protocol Version Date 03/06/09)
- 04/08/09: CIRB Approval Letter for Revision 3 (Protocol Version Date 03/06/09)
- Protocol Version Date 03/06/09
- Informed Consent Document for Protocol Version Date 03/06/09 [Rev3]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 03/06/09
- 04/03/09: Primary Reviewer 1 Comments
- 04/03/09: Minutes - Revision 3

### **Serious Adverse Events**

**Study: CALGB 30607**

**SAE Posted: 1434562, 1434562 FU1**

**Study: CALGB 80405**

**SAE Posted: 08-02-15603 FU2, 08-02-15765 FU3, 09-02-15897 FU1, 09-02-15962 FU1, 09-02-15966 FU1, 1205368 FU1, 1324148, 1433885, 1477246 FU1, 1636469 FU1, 1729567 FU1, 1803957 FU1, 1809808 FU1, 1843518 FU2, 1881593, 1996104, 273064**

**Study: CALGB 90206**

**SAE Posted: 1205368 FU1, 1324148, 1433885, 1477246 FU1, 1636469 FU1, 1729567 FU1, 1803957 FU1, 1809808 FU1, 1843512 FU2, 1881593, 1996104**

**Study: CALGB 90401**

**SAE Posted: 1205386 FU1, 1324148, 1433885, 1477246 FU1, 1636469 FU1, 1729567 FU1, 1803957 FU1, 1809808 FU1, 1843518 FU2, 1881593, 1996104, 273064**

**Study: ECOG E1105**



**SAE Posted: 1034535, 1201753, 1324148 FU1, 1360351, 1433885 FU1, 1475911 FU1, 1580693 FU1, 1820686 FU1, 1843518 FU2, 1859262 FU1, 1951869 FU1, 1996104**

**Study: ECOG E1505**

**SAE Posted: 1034535, 1118620, 1118620 FU1, 1201753, 1205368 Fu1, 1324148, 1324148 FU1, 1360351, 1433885, 1433885 FU1, 1475911, 1475911 FU1, 1580693, 1580693 FU1, 1636469 FU1, 1729567 FU1, 1803957 FU1, 1820686 FU1, 1843518 FU2, 1859262 FU1, 1951869 FU1, 1996104, 273064**

**Study: ECOG E1A05**

**SAE Posted: 1203812 FU1, 1203812 FU2, 1358268 FU1, 1567424 FU1, 1628411**

**Study: ECOG E1A06**

**SAE Posted: 1358268 FU1, 1628411**

**Study: ECOG E2603**

**SAE Posted: 1047408, 1434562, 1434562 FU1, 1475911, 1475911 FU1, 1642009, 1642009 FU1, 1820686 FU1**

**Study: ECOG E2805**

**SAE Posted: 1047408, 1140081, 1434562, 1434562 FU1, 1475911, 1475911 FU1, 1642009, 1642009 FU1, 1820686 FU1**

**Study: ECOG E2902**

**SAE Posted: 1117466 FU1, 1156086 FU1, 1364650, 1659029, 1659029FU1**

**Study: ECOG E2100**

**SAE Posted: 1034535, 1118620, 1201753, 1205368 FU1, 1324148, 1324148 FU1, 1360351, 1433885 FU1, 1475911, 1475911 FU1, 1580693, 1580693 FU1, 1636469 FU1, 1729567 FU1, 1820686 FU1, 1843518 FU2, 1859262 FU1, 1951869 FU1, 1996104, 273064**

**Study: ECOG E4599**

**SAE Posted: 1843518 FU2, 1859262 FU1, 1996104**

**Study: ECOG E5103**

**SAE Posted: 1034535, 1118620, 1201753, 1205368 FU1, 1324148 FU1, 1360351, 1433885 FU1, 1475911 FU1, 1580693 FU1, 1820686 FU1, 1859262 FU1, 1951869 FU1, 1996104, 273064**

**Study: SWOG S0502**

**SAE Posted: 1118620, 1118620 FU1, 1205368, 1205368 FU1, 1324148, 1433885, 1477246 FU1, 1580693, 1636469 FU1, 1729567, 1729567 FU1, 1803957, 1803957 FU1, 1809808, 1809808 FU1, 1843518 FU2, 1881593, 270229**



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

### **COG-ANBL0322**

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/28/07)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/07)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 03/28/07
- Informed Consent Document for Protocol Version Date 03/28/07

#### **Correction:**

Corrected study title COG-ANBL0322, posted on May 15, 2009 Study Activity Update. Original posting incorrectly listed the Continuing Review as COG-ANBL0332.

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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).