



## **NCI Central IRB Study Activity Update June 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. **\*\***



## **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**

### **Study Number**

Initial Review Approval

Documents Posted:

- NONE

## **Pediatric CIRB Studies**

### **Study Number**

Initial Review Approval

Documents Posted:

- NONE

## **Other Activity Posted:**

### **CALGB-80101**

Amendment Review (AR): **\*\*Closed to Accrual – Effective May 29, 2009 at 5:00 pm EST\*\***

Documents Posted:

- 05/29/09: Closure to Accrual Notice
- 05/29/09: Acknowledgement of Closure to Accrual

### **CALGB-80405**

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/27/08)
- 06/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/27/08)
- 05/04/09: Continuing Review Reminder Notice
- Protocol Version Date 08/27/08



- CIRB's Informed Consent Document for Protocol Version Date 08/27/08 [CR09]
- 06/04/09: Primary Reviewer 1 Comments
- 02/10/09: Journal of Clinical Oncology (Hecht)
- 02/05/09: The New England Journal of Medicine (Tol)
- November 2008 - Study Summary
- 11/14/08: DSMB Report

#### **COG-AALL0433**

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- 05/07/09: Minutes - Group Response to Continuing Review

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

#### **COG-AALL0434**

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- 05/07/09: Minutes - Group Response to Continuing Review

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

#### **COG-AALL06N1**

Amendment Review (AR): **Acknowledgment of Tracked-Changes Consent Document regarding AALL06N1 Amendment #1B**

Documents Posted:

- 06/01/09: AALL06N1 CIRB Acknowledgement of Tracked-Changes Consent Document regarding AALL06N1 Amendment #1B
- Tracked Changes for Informed Consent Document 1 for Protocol Version Date 10/02/08

#### **COG-AALL0622**

Amendment Review (AR): **Acknowledgement of COG AALL0622 Updated Investigator's Brochure for Dasatinib (BMS-354825) Version No. 8 (Release Date 11/12/2008)**

Documents Posted:



- 06/04/09: CIRB Acknowledgement of Updated Investigator's Brochure

#### **COG-AALL0631**

Amendment Review (AR): [Acknowledgment of COG AALL0631 Updated Investigator's Brochure Lestaurtinib](#)

Documents Posted:

- 05/28/09: CIRB Acknowledgement of Updated Investigator's Brochure

#### **COG-AALL07P4**

Amendment Review (AR): [Acknowledgement of COG AALL07P4 Updated Investigator's Brochure for EZN-2285 v4.0](#)

Documents Posted:

- 05/29/09: CIRB Acknowledgement of Updated Investigator's Brochure

#### **COG-AAML0523**

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/06/08)
- 06/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/06/08)
- 06/01/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/06/08)
- 05/29/09: CIRB Approval Pending Modification Letter (Protocol Version Date 05/06/08)
- 04/07/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/06/08
- Informed Consent Document for Protocol Version Date 05/06/08
- 05/14/09: Primary Reviewer 1 Comments
- Spring 2009 Study Progress Report
- 11/06/08: DSMC Report
- 08/25/08: Study Progress Report

#### **COG-AAML06P1**

Amendment Review (AR): [Acknowledgment of COG AAML06P1 Updated Investigator's Brochure Lestaurtinib](#)

Documents Posted:

- 05/27/09: CIRB Acknowledgement of Updated Investigator's Brochure



#### **COG-ACNS0334**

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- 04/21/09: Minutes - Group Response to Tabled Continuing Review

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

#### **COG-ADVL0221**

Amendment Review (AR): **Acknowledgment of COG ADVL0221 Updated Investigator's Brochure for Yondelis (Trabectedin) Edition 5 (Dated April 27, 2009)**

Documents Posted:

- 06/04/09: CIRB Acknowledgement of Updated Investigator's Brochure

#### **COG-ADVL0525**

**\*\*Partial Closure for Disease Strata: Osteosarcoma and Ependymoma – Effective May 22, 2009\*\***

Amendment Review (AR): **Acknowledgement of COG ADVL0525 Partial Closure for Disease Strata: Osteosarcoma and Ependymoma (05/22/09)**

Documents Posted:

- 05/29/09: CIRB Acknowledgement - ADVL0525 Partial Closure for Disease Strata Osteosarcoma and Ependymoma
- 05/22/09: COG Notice ADVL0525 Partial Closure for Disease Strata Osteosarcoma and Ependymoma

#### **COG-ADVL0821**

**\*\*Partial Closure for Disease Strata: Osteosarcoma, Ewing Sarcoma/Peripheral PNET, and Rhabdomyosarcoma by COG of ADVL0821 – Effective May 22, 2009\*\***

Amendment Review (AR): **Acknowledgement of COG ADVL0821 Partial Closure for Disease Strata: Osteosarcoma, Ewing Sarcoma/Peripheral PNET, and Rhabdomyosarcoma (05/22/09)**

Documents Posted:

- 05/29/09: CIRB Acknowledgement - ADVL0821 Partial Closure for Disease Strata Osteosarcoma, Ewing Sarcoma/Peripheral PNET, and Rhabdomyosarcoma



- 05/22/09: COG Notice ADVL0821 Partial Closure for Disease Strata Osteosarcoma, Ewing Sarcoma/Peripheral PNET, and Rhabdomyosarcoma

#### **COG-AOST06B1**

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-AOST06P1**

**\*\* Study Reactivation by COG - Effective May 25, 2009\*\***

Amendment Review (AR): **Amendment #2 and Reactivation (Protocol Version Date 04/27/09)**

Documents Posted:

- CIRB Application (Protocol Version Date 04/27/09)
- 05/29/09: CIRB Acknowledgement of COG AOST06P1 Amendment #2 and Reactivation (Protocol Version Date 04/27/09)
- 05/25/09: COG AOST06P1 Amendment #2 Reactivation Memo
- 05/12/09: CIRB Approval of COG AOST06P1 Amendment #2 (Protocol Version Date 04/27/09)
- 04/27/09: COG Change Memo (Protocol Version Date 04/27/09)
- Protocol Version Date 04/27/09
- Protocol Version Date 04/27/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 04/27/09

#### **COG-AREN0321**

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- 04/21/09: Minutes - Group Response to Continuing Review

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

#### **COG-AREN0532**

Continuing Review (CR): Continuing Review May 2009

Documents Posted:



- CIRB Continuing Review Application (Protocol Version Date 10/16/07)
- 06/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/16/07)
- 06/03/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/16/07)
- 05/29/09: CIRB Approval Pending Modification Letter (Protocol Version Date 10/16/07)
- 04/07/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/16/07
- Informed Consent Document for Protocol Version Date 10/16/07 - Observation Arm
- Informed Consent Document for Protocol Version Date 10/16/07 - Chemotherapy Arm
- 05/14/09: Primary Reviewer 1 Comments
- 10/07/08: DSMC Report
- 08/25/08: Study Progress Report

#### **COG-ARST0332**

Amendment Review (AR): Amendment #1B (Protocol Version Date 04/07/09)

Documents Posted:

- CIRB Application (Protocol Version Date 04/07/09)
- 06/09/09: CIRB Acknowledgement of COG ARST0332 Posting of Amendment #1B
- 06/08/09: COG ARST0332 Amendment #1B Activation Memo
- 05/29/09: CIRB Approval of COG ARST0332 Amendment #1B (Protocol Version Date 04/07/09)
- 04/07/09: COG Change Memo (Protocol Version Date 04/07/09)
- Protocol Version Date 04/07/09
- Protocol Version Date 04/07/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 04/07/09
- 05/14/09: Primary Reviewer 1 Comments

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.**

#### **ECOG-E1302**



Amendment Review (AR): CIRB Acknowledgement Updated Iressa Investigator's Brochure Version 14

Documents Posted:

- 06/09/09: CIRB Acknowledgement of E1302 updated Iressa Investigator Brochure version 14 dated 02/25/09

**ECOG-E1900**

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/14/08)
- 06/10/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/14/08)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 05/14/08
- CIRB's Informed Consent Document (Protocol Version Date 05/14/08) [CR09]
- 06/04/09: Primary Reviewer 1 Comments
- June 2009 - Study Summary
- October-November 2008 DMC Recommendations
- Biology of Blood & Marrow Transplantation - February 2008 Article
- Clinical Cancer Letter - November 2008 Article
- Leukemia Research - 2006 Article
- Biology of Blood & Marrow Transplantation - February 2005 Article

**GOG-0218**

Amendment Review (AR): Revision #6 (Protocol Version Date 05/18/09)

Documents Posted:

- 05/18/09: GOG Change Memo (Protocol Version Date 05/18/09)
- CIRB Application (Protocol Version Date 05/18/09)
- Summary of CIRB Application Revisions (Protocol Version Date 05/18/09)
- 05/26/09: CIRB Approval Letter Revision 6 (Protocol Version Date 05/18/09)
- Protocol Version Date 05/18/09
- Protocol Version Date 05/18/09 (Highlighted)
- Appendix I: FIGO Stage Grouping for Primary Carcinoma of the Ovary
- Appendix II: Glossary of Terms
- Appendix III: NCI Standard Protocol Language
- Appendix IV: Electronic Patient Registration and Randomization
- Appendix V: Anaphylaxis Precautions



- Appendix VI: Specimen Procedures
- Appendix VII: Laboratory Procedures
- Informed Consent Document for Protocol Version Date 05/18/09 [Rev 6]

#### **GOG-0240**

Amendment Review (AR): Informational Memo—Errors in Informed Consent and Section 5.222

Documents Posted:

- 06/02/09: CIRB Acknowledgement of GOG 0240 Informational Memo
- 05/26/09: GOG 0240 Informational Memo

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/10/09)
- 6/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/10/09)
- 05/04/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 03/10/09
- CIRB's Informed Consent Document for Protocol Version Date 03/10/09 [CR09]
- 06/04/09: Primary Reviewer 1 Comments

#### **NCCTG-N0723**

Amendment Review (AR): Addendum #3 (Protocol Version Date 05/05/09)

Documents Posted:

- 05/05/09: Change Memo (Protocol Version Date 05/05/09)
- CIRB Application (Protocol Version Date 05/05/09)
- Summary of CIRB Application Revisions (Protocol Version Date 05/05/09)
- 05/11/09: CIRB Addendum 3 Approval Letter (Protocol Version Date 05/05/09)
- CAEPR for Erlotinib (Version 2.2. April 7, 2009)
- OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol Version Date 05/05/09
- Informed Consent Document for Protocol Version Date 05/05/09 [Ad3]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 05/05/09

#### **NCIC CTG-BR.19**



Amendment Review (AR): CIRB Acknowledgement of CIRB Updated Iressa Investigator's Brochure Version 14

Documents Posted:

- 06/09/09: CIRB Acknowledgement of BR.19 Updated Investigators Brochure for Iressa dated 02/25/09

**NSABP-B-39/RTOG-0413**

Amendment Review (AR): **Closure of Accrual - BAHO Substudy: Quality of Life (QOL), Cosmesis, and Digital Photos Assessments**

Documents Posted:

- 06/02/09: CIRB Acknowledgement of Receipt of BAHO Substudy Closure
- 05/27/09: BAHO Substudy Closure Memo

**RTOG-0320**

Amendment Review (AR) Amendment #7 (Protocol Version Date 04/24/09)

Documents Posted:

- Change Memo (Protocol Version Date 04/24/09)
- CIRB Application (Protocol Version Date 04/24/09)
- Summary of CIRB Application Revisions (Protocol Version Date 04/24/09)
- 05/11/09: CIRB Amendment 7 Approval Letter (Protocol Version Date 04/24/09)
- OHRP Letter Dated 09/29/08
- Protocol Version Date 04/24/09
- Informed Consent for Protocol Version Date 04/24/09 [Am7]

**RTOG-0436**

Amendment Review (AR) 05/28/09 Update (Protocol Version Date 02/13/09)

Documents Posted:

- 05/28/09: Change Memo (Protocol Version Date 02/13/09)
- 06/03/09: CIRB Approval Letter for May 28, 2009 Update (Protocol Version 02/13/09)
- Protocol Version Date 02/13/09
- Informed Consent for Protocol Version Date 02/13/09 Update of 05/28/09

**RTOG-BR-0118**

Amendment Review (AR) CIRB Closure Due to Study Completion

Documents Posted:



- 06/09/09: CIRB Closure-Due to Study Completion

#### **SWOG-S0232**

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/01/07)
- 06/01/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/01/07)
- 04/07/09: Continuing Review Reminder Notice
- Protocol Version Date 06/01/07
- Informed Consent Document for Protocol Version Date 06/01/07
- 04/07/09: DSMC Minutes
- April 2009 - Study Summary

#### **SWOG-S0337**

Amendment Review (AR): Revision #2 (Protocol Version Date 05/15/09)

Documents Posted:

- 05/15/09: Change Memo (Protocol Version Date 05/15/09)
- CIRB Application (Protocol Version Date 05/15/09)
- Summary of CIRB Application Revisions (Protocol Version Date 05/15/09)
- 05/22/09: CIRB Approval Letter Revision 2 (Protocol Version Date 05/15/09)
- Protocol Version Date 05/15/09
- CIRB's Informed Consent Document for Protocol Version Date 05/15/09 [Rev2]
- CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 05/15/09)

#### **SWOG-S0521**

Amendment Review (AR): Revision #4 (Protocol Version Date 04/30/09)

Documents Posted:

- 06/01/09: Change Memo (Protocol Version Date 04/30/09)
- CIRB Application (Protocol Version Date 04/30/09)
- Summary of CIRB Application Revisions (Protocol Version Date 04/30/09)
- 05/20/09: CIRB Revision 4 Approval Letter (Protocol Version Date 04/30/09)
- Protocol Version Date 04/30/09
- Informed Consent Document for Protocol Version Date 04/30/09 [Rev4]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 04/30/09



## **Serious Adverse Events**

### **Study: ECOG E5202**

**SAE Posted: 1034535, 1118620, 1118620 FU1, 1201753, 1205368 FU1, 1324148, 1324148 FU1, 1354425 FU1, 1360351, 1433885, 1433885 FU1, 1475911, 1475911 FU1, 1580693, 1580693 FU1, 1636469 FU1, 1729567, 1729567 FU1, 1803957 FU1, 1809808, 1820686 FU1, 1843518 FU2, 1859262 FU1, 1951869 FU1, 1996104, 267119 FU2, 270229, 273064**

### **Study: ECOG E5204**

**SAE Posted: 1034535, 1118620, 1118620 FU1, 1201753, 1205368 FU1, 1324148, 1324148 FU1, 1354425 FU1, 1360351, 1433885, 1433885 FU1, 1475911, 1475911 FU1, 1580693, 1580693 FU1, 1636469 FU1, 1729567, 1729567 FU1, 1803957 FU1, 1809808, 1820686 FU1, 1843518 FU2, 1859262 FU1, 1951869 FU1, 1996104, 270229, 273064**

### **Study: NSABP B-34**

**SAE Posted: 200812671 SU73 FU3, 200815097 SU79 FU2, 200815097 SU79 FU3, 200831463 SU99 FU1, 200833071 SU100 FU1, 200836438 SU109 FU1, 200839971 SU115 FU2, 200839971 SU115 FU5, 200912953 SU119, 200912953 SU119 FU1, 200913537 SU117, 200913597 SU120, 200913715 SU118, 200913939 SU121 FU1, 200914480 SU122, 200915232 SU124, 200916112 SU126, 200916296 SU123, 200916443 SU125, TR-2007-006800 SU44 FU2**

### **Study: NSABP B-40**

**SAE Posted: 264828, 264828 FU1, 265688 FU1, 268723 FU1, 270309, 272529 FU1, 272529 FU2, 272778, 272778 FU1, 273064 FU1, 275439, 275439 FU2, 275439 FU3, 275662, 275904, 276863, 278120, 278120 FU2, 278858, DE200702001788 FU2, DE200902001955, DE200902002200, DE200902002201, FR200806005794 FU1, FR200902003893, FR200903000570, JP200812005805, JP200812005805 FU1, NL200811000680, US200605004414**

### **Study: RTOG 0436**

**SAE Posted: 08-02-15483 FU1, 08-02-15541 FU3, 08-02-15660 FU2, 08-02-15765 FU2, 08-02-15765 FU3, 08-02-15831 FU1, 09-02-15897 Fu1, 09-02-15897 FU2, 09-02-15898, 09-02-15898 FU1, 09-02-15929 FU1, 09-02-15929 FU2, 09-02-15962 FU1, 09-02-15966 FU1, 09-02-15973 FU1, 09-02-15982, 09-02-15982 FU1, 09-02-15989 Fu1, 09-02-16124 FU1, 09-02-16124 FU2, 09-02-16130 FU1, 09-02-16130 FU2, 09-02-16131, 09-02-16131 Fu1, 09-02-16131 FU2, 09-02-16203 FU1, 09-02-16203 FU2, 09-02-16296, 09-02-16296 Fu1, 09-02-16306, 09-02-16306 FU1, 09-02-16382 FU1, 09-02-16435 FU2, 09-02-16468 FU1, 09-02-16476 FU1, 09-02-16481 FU1, 09-02-16482**



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

None

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).