



## NCI Central IRB Study Activity Update July 31, 2007

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**

#### **SWOG – S0337**

Initial Review 2006 Approval  
Documents Posted:

- Protocol Version Date 11/22/06
- Protocol Version Date 10/02/06
- Protocol Version Date 06/07/06
- Protocol Submission Worksheet
- Informed Consent Form for Protocol Version Date 11/22/06
- CIRB Application (Protocol Version Date 11/22/06)
- Summary of CIRB Application Revisions - Protocol Version Date 11/22/06
- CIRB Application (Protocol Version Date 10/02/06)
- Summary of CIRB Application Revisions - Protocol Version Date 10/02/06
- CIRB Application (Protocol Version Date 06/07/06)
- 10/16/06: Primary Reviewer 1 Comments
- 09/01/06: Primary Reviewer 1 Comments
- 01/08/07: CIRB Final Approval
- 11/22/06: Group Response Letter
- 11/09/06: CIRB Approval Pending Modification
- 10/02/06: Group Response Letter
- 09/11/06: CIRB Table of Initial Review
- 06/07/06: Letter from the Group
- 10/16/06: Minutes: Initial Review - Group Response to Tabled Action
- 09/01/06: Minutes: Initial Review

### **Other Activity Posted:**

#### **COG – AALL05B1**

Continuing Review (CR): June 2007  
Documents Posted:

- 07/17/07: CIRB Approval for Continuation and Amendment
- 07/13/07: Response to Pediatric CIRB
- Protocol Version Date 07/13/07
- Protocol Version 07/13/07 – Highlighted
- Informed Consent Form for Protocol Version Date 07/13/07
- CIRB Application Protocol Version Date 07/13/07



### **COG – AHOD0431**

Amendment Review (AR): Amendment #1  
Documents Posted:

- CIRB Application Version 05/11/07
- 07/10/07: CIRB Full Board Approval Letter
- Protocol Version Date 05/11/07 - Highlighted
- Protocol Version Date 05/11/07
- Informed Consent Form for Protocol Version 05/11/07: Relapse Treatment
- Informed Consent Form for Protocol Version 05/11/07: Initial Treatment

### **COG – ANBL0421**

Amendment Review (AR): Amendment #1  
Documents Posted:

- CIRB Application Protocol Version Date 06/21/07
- CIRB Application Protocol Version Date 03/26/07
- 07/05/07: Approved Amendment
- 06/21/07: Response Letter
- 05/24/07: Full Board Approval Pending Modification
- 03/26/07: Letter to Dr. Montello
- Protocol Version Date 06/21/07
- Protocol Version Date 06/21/07 - Highlighted
- Protocol Version Date 03/26/07
- Protocol Version Date 03/26/07 – Highlighted
- Informed Consent Form for Protocol Version Date 06/21/07 [per June 2007 CR]

### **COG – ARST0431**

Continuing Review (CR): June 2007  
Documents Posted:

- 07/13/07: CIRB Approval for Continuation
- 07/02/07: Changes to Protocol
- 06/20/07: Full Board CIRB Approval per June 2007 CR
- 03/30/07: Study Committee Progress Report
- Protocol Version Date 06/26/07
- Informed Consent Form for Protocol Version 06/26/07
- CIRB Application Protocol Version Date 06/26/07
- CIRB Continuing Review Application Protocol Version Date 02/23/07

Amendment Review (AR): Amendment #3 (dated 06/26/07)  
Documents Posted:

- CIRB Application Protocol Version Date 06/26/07



- Continuing Review Application Protocol Version Date 02/23/07
- 07/13/07: CIRB Approval for Continuation
- 07/02/07: Changes to Protocol
- 06/20/07: Full Board CIRB Approval per June 2007 CR
- Protocol Version Date 06/26/07
- Protocol Version Date 06/26/07 – Highlighted
- Informed Consent Form for Protocol Version 06/26/07

#### **CALGB – 40101**

Continuing Review (CR): July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/20/07)
- 07/27/07: Approval Letter
- Protocol Version Date 02/20/07
- Informed Consent Form for Protocol Version Date 02/20/07 [per CR 07]
- Study Summary

#### **CALGB – 50303**

Amendment Review (AR): Update #5

Documents Posted:

- Protocol Update
- Summary of Application Revisions
- CIRB Application (Protocol Version Date 04/17/07)
- 06/18/07: Approval Letter
- 06/06/07: Letter from the Group
- 06/05/07: CIRB Approval Pending Modification
- Protocol Version Date 04/17/07
- Informed Consent Form for Protocol Version Date 04/17/07

#### **CALGB – 90104**

Amendment Review (AR): Update #4

Documents Posted:

- Protocol Update
- 06/26/07: Approval Letter
- Protocol Version Date 03/26/07

#### **CALGB/SWOG - 80405**

Amendment Review (AR): Update #3

Documents Posted:

- CALGB: Pharmacogenomic Submission And Quality Assurance Form



- CALGB: Solid Tumor Evaluation Form
- Protocol Update (Protocol Version Date 06/13/07)
- Protocol Update (Protocol Version Date 03/28/07)
- Summary of CIRB Application Revisions (Protocol Version Date 06/13/07)
- Summary of CIRB Application Revisions (Protocol Version Date 03/28/07)
- CIRB Application (Protocol Version Date 06/13/07)
- CIRB Application (Protocol Version Date 03/28/07)
- 07/02/07: Approval Letter
- 06/13/07: Group Response Letter
- 05/30/07: CIRB Approval Pending Modification
- Protocol Version Date 06/13/07
- Protocol Version Date 03/28/07
- Informed Consent Form for Protocol Version Date 06/13/07

#### **ECOG – E5204**

Amendment Review (AR): Addendum #2

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 05/31/07)
- 06/26/07: Approval Letter
- 05/31/07: Letter from the Group
- Protocol Version Date 05/31/07
- Informed Consent Form for Protocol Version Date 05/31/07

#### **GOG – 0204**

Continuing Review (CR) July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/06/06)
- 07/17/07: Approval Letter
- Protocol Version Date 09/06/06
- 07/22/06: DSMB Minutes
- Appendix I FIGO
- Appendix II QOL Questionnaire Sample
- Statistical Report

Amendment Review (AR): Acknowledgement of Study Closure

Documents Posted:

- 07/05/07: CIRB Acknowledgement of Receipt
- 04/27/07: Closure Memo



### **GOG – 0209**

Continuing Review (CR) July 2007  
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/18/06)
- 07/27/07: Approval Letter
- Protocol Version Date 12/18/06
- Informed Consent Form for Protocol Version Date 12/18/06 [per CR 07]
- Study Summary
- Appendix I
- Appendix II
- Appendix III

### **GOG – 0218**

Amendment Review (AR): Protocol GOG-0218 - INFORMATIONAL MEMO  
Documents Posted:

- 07/27/07: CIRB Acknowledgement of Receipt
- 04/16/07: To All Principal Investigators, Nurses and Data Managers

### **NCCTG – N0147**

Amendment Review (AR): Addendum #6  
Documents Posted:

- Summary of CIRB Application Revisions (Protocol Version Date 05/22/07)
- Summary of CIRB Application Revisions (Protocol Version Date 02/07/07)
- CIRB Application (Protocol Version Date 05/22/07)
- CIRB Application (Protocol Version Date 02/07/07)
- 06/06/07: Approval Letter
- 05/22/07: Response to CIRB Review
- 05/04/07: CIRB Approval Pending Modification
- Protocol Version Date 05/22/07 (Part 1)
- Protocol Version Date 05/22/07 (Part 2)
- Protocol Version Date 05/22/07 (Part 3)
- Protocol Version Date 02/07/07
- 04/06/07: Minutes: Amendment Review

### **NCIC CTG – MA.27B**

Amendment Review (AR): Amendment #2  
Documents Posted:

- Summary of Changes (Protocol Version Date 05/22/07)
- Summary of CIRB Application Revisions (Protocol Version Date 12/04/06)
- Summary of Changes (Protocol Version Date 12/04/06)
- CIRB Application (Protocol Version Date 12/04/06)



- 05/23/07: Approval Letter
- 04/12/07: CIRB Approval Pending Modification
- 05/18/07: Letter from the Group
- Protocol Version Date 05/22/07
- Protocol Version Date 12/04/06
- Informed Consent Form for Protocol Version Date 05/22/07
- 03/02/07: Minutes: Amendment Review

#### **NSABP - B - 35**

Amendment Review (AR): Amendment #4

Documents Posted:

- Summary of CIRB Application Revisions
- Summary Of Protocol Changes (Protocol Version Date 03/26/07)
- CIRB Application (Protocol Version Date 03/26/07)
- 04/13/07: Approval Letter
- 03/28/07: Letter from the Group
- Protocol Version Date 03/26/07

#### **RTOG – 0421**

Continuing Review (CR) July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/14/07)
- 07/20/07: Approval Letter
- Protocol Version Date 02/14/07
- 01/17/07: DMC Minutes
- Study Summary Report

#### **RTOG - BR - 0118**

Continuing Review (CR) July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/31/03)
- 07/25/07: Approval Letter
- Protocol Version Date 10/31/03
- 01/17/07: DMC Minutes
- Study Summary

#### **SWOG – S0337**

Amendment Review (AR): Amendment #0

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 05/01/07)



- 06/07/07: Approval Letter
- 05/01/07: Amendment #0 for Prior Approval
- Protocol Version Date 05/01/07
- Informed Consent Form for Protocol Version Date 05/01/07

### **SWOG – S9925**

Continuing Review (CR) July 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/13/06)
- 07/17/07: Approval Letter
- Protocol Version Date 12/13/06
- Study Summary

### **Serious Adverse Events**

**Study: CALGB 80203**

**SAE's Posted: DDL # 243 (1) / 07-02-11207, 07-02-11452,**

**Study: CALGB 80303**

**SAE's Posted: 240156 (2)**

**Study: CALGB-SWOG 80405**

**SAE's Posted: DDL # 243 (1) / 07-02-11207, 07-02-11452, 240156 (2)**

**Study: CALGB 90206**

**SAE's Posted: 240156 (2)**

**Study: CALGB 90401**

**SAE's Posted: 240156 (2)**

**Study: ECOG 2100**

**SAE's Posted: 240156 (1), 240156 (2)**

**Study: ECOG 2603**

**SAE's Posted: 1273968, 1333296 (1), 1989015**

**Study: ECOG E2805**

**SAE's Posted: 1273968, 1333296 (1), 1989015, 2006099946 (3), 2007020163**

**Study: ECOG 3200**

**SAE's Posted: 240156 (1), 240156 (2)**

**Study: ECOG E4A03**

**SAE's Posted: 1784436**



**Study: ECOG 4599**  
**SAE's Posted: 240156 (1), 240156 (2)**

**Study: ECOG 5202**  
**SAE's Posted: 240156 (1), 240156 (2)**

**Study: ECOG 5204**  
**SAE's Posted: 240156 (1), 240156 (2)**

**Study: GOG-0218**  
**SAE's Posted: 240156 (2)**

**Study: NCIC CTG MA.27**  
**SAE's Posted: 2007026268, 2007036293**

**Study: NSABP B-34**  
**SAE's Posted: DE-2006-032513 / Safety Update # 41 (3), GB-2007-012082 / Safety Update # 46, GB-2007-014121 / Safety Update # 47, US-2007-019013 / Safety Update # 48**

**Study: NSABP B-38**  
**SAE's Posted: DE200702001788 (1), DE200705001017, DE200705001017 (1), GB200704000162 (1)**

**Study: NSABP B-40**  
**SAE's Posted: 235492 (1), 238168 (3), 240156 (1), 240156 (3), DE200702001788 (1), DE200705001017, DE200705001017 (1), GB200704000162 (1)**

**Study: NSABP C-08**  
**SAE's Posted: 240156 (3)**

**Study: RTOG 0320**  
**SAE Posted: 1998-12-0033 (2), 2006SP004547 (4), 2007SP003140 (6), 2007SP006582, 2007SP006582 (1), 2007SP006588**

**Study: RTOG 0525**  
**SAE Posted: 1998-12-0033 (2), 2006SP004547 (4), 2007SP003140 (6), 2007SP006582, 2007SP006582 (1), 2007SP006588**

**Study: SWOG S0205**  
**SAE Posted: DDL # 249 / 07-02-11728**

**Study: SWOG S0303**



**SAE's Posted: 240156 (2)**

**Study: SWOG S0307**

**SAE Posted: GB-2007-012082 / Safety Update # 46, GB-2007-014121 / Safety Update # 47**

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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).