



## NCI Central IRB Study Activity Update June 30, 2006

The CIRB is distributing this study activity update to notify its participating institutions of recent information and documentation for current CIRB protocols. Information about study-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 study-specific information in this email refers to amendment/revision documentation approved by CIRB and NCI CTEP. Information about new studies refers to studies 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@ctisinc.com](mailto:ncicirbcontact@ctisinc.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@ctisinc.com](mailto:ncicirbcontact@ctisinc.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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### Study Specific Documentation (listed by study)

**\*\*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 S0334**

Initial Review 2005

Documentation Posted:

- Protocol, Version 6/19/06
- Protocol, Version 8/15/05
- Informed Consent for Protocol Version 06/19/06
- Revised CIRB Application (for Protocol Version 6/19/06)
- Summary of CIRB Application Revisions
- CIRB Application (for Protocol Version 8/15/05)
- 6/21/06, Final Approval (Version dated 6/19/06): Study Chair
- 6/21/06, Final Approval (Version dated 6/19/06): Local IRB
- 6/19/06, SWOG Response to CIRB Inquiry
- 6/12/06, Approval Pending Modification (Version dated 8/15/05)

## **Pediatric CIRB Studies**

### **COG AREN0321**

Initial Review 2005

Documentation Posted:

- Protocol Version 02/06/06
- Protocol Version 02/06/06, Highlighted Changes
- Protocol Version 12/09/05
- Protocol Version 12/09/05, Highlighted Changes
- Protocol Version 05/23/05
- Informed Consent for Protocol Version 02/06/06: Observation
- Informed Consent for Protocol Version 02/06/06: Regimen DD-4A
- Informed Consent for Protocol Version 02/06/06: Window Therapy PV
- Informed Consent for Protocol Version 02/06/06: Regimen I PV
- Informed Consent for Protocol Version 02/06/06: Regimen UH1
- CIRB Application Version 02/06/06
- CIRB Application Version 12/09/05
- CIRB Application Version 05/23/05
- 01/12/06: Member Comments
- 01/12/06: Primary Reviewer 2 Comments
- 01/12/06: Primary Reviewer 3 Comments
- 01/12/06: Primary Reviewer 1 Comments
- 07/28/05 Primary Reviewer 1 Comments
- 07/28/05: Primary Reviewer 2 Comments
- 07/28/05: Pharmacist Comments
- 07/28/05 Primary Reviewer 3 Comments



- 07/28/05: Member 1 Comments
- 07/28/05: Member 2 Comments
- 07/28/05: Member 3 Comments
- 2/10/06: CIRB Approval (Protocol Version 2/06/06): Study Chair
- 2/10/06: CIRB Approval (Protocol Version 2/10/06): Local IRB
- 2/09/06: COG Response to Approval Pending Modification
- 2/02/06: Approval Pending Modification (Protocol Version 12/09/05)
- 12/09/05: COG Response (Protocol Version 12/09/05)
- 8/30/05: CIRB Tabled Letter (Protocol Version 5/23/05)
- 01/12/06: Group Response Meeting Minutes
- 07/28/05: Initial Review Meeting Minutes

Amendment Review: Protocol Version 05/01/06  
Documentation Posted:

- 05/02/06 Change Memo
- CIRB Application Version 05/01/06
- 06/19/06: Study Activation
- 06/19/06: CIRB Acknowledgement of Activation
- 05/25/06: CIRB Approval (Protocol Version 05/01/06): Local IRB
- 05/25/06: CIRB Approval (Protocol Version 05/01/06): Study Chair
- Protocol Version 05/01/06, Highlighted Changes
- Protocol Version 05/01/06
- Informed Consent for Protocol Version 05/01/06: Regimen DD-4A
- Informed Consent for Protocol Version 05/01/06: Observation
- Informed Consent for Protocol Version 05/01/06: Regimen 1
- Informed Consent for Protocol Version 05/01/06: UH1
- Informed Consent for Protocol Version 05/01/06: Window
- 05/25/06: Primary Reviewer 1 Comments

### **Other Activity Posted:**

#### **CALGB 30102**

Continuing Review August 2006  
Documentation posted:

- 06/21/06, Continuing Review Notice for August 2006

#### **CALGB 49907**

Continuing Review August 2006  
Documentation posted:

- 06/21/06, Continuing Review Notice for August 2006



**CALGB 90401**

Continuing Review August 2006  
Documentation posted:

- 06/21/06, Continuing Review Notice for August 2006

**COG AALL0331**

Continuing Review September 2006  
Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

**COG AALL03B1**

Continuing Review September 2006  
Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

Amendment #2 (Protocol Version 03/20/06)  
Documentation posted:

- 03/20/06, Change Memo
- CIRB Application Version 03/20/06
- 06/22/06: CIRB Approval (Protocol Version 03/20/06): Study Chair
- 06/22/06: CIRB Approval (Protocol Version 03/20/06): Local IRB
- Activation of Amendment #2 (Protocol Version 03/20/06)
- Protocol Version 03/20/06
- Protocol Version 03/20/06, Highlighted Changes
- Informed Consent for Protocol Version 03/20/06

CIRB Acknowledgement of Revised Eligibility and Pre-Induction Worksheet  
Documentation posted:

- 06/30/06, Revised Eligibility and Pre-Induction Worksheet
- 07/05/06, CIRB Acknowledgement of Revised Eligibility and Pre-Induction Worksheet

**COG AAML0121**

Continuing Review July 2006  
Documentation posted:

- CIRB Continuing Review Application Version 10/21/05
- 06/22/06, CIRB Approval (Protocol Version 10/21/05): Study Chair
- 06/22/06, CIRB Approval (Protocol Version 10/21/05): Local IRB
- Protocol Version 10/21/05



- Informed Consent for Protocol Version 10/21/05 [per 2006 CR]
- Study Committee Progress Report Dated 02/23/06
- DSMC Report Dated 10/07/05

#### **COG ACNS0224**

Continuing Review September 2006

Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

#### **COG ACNS0423**

Continuing Review September 2006

Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

#### **COG ADVL0524**

Amendment Review: CIRB Acknowledgement of Posting

Documentation posted:

- 06/26/06, CIRB Acknowledgement of error in Schwartz formula conversion to micromolar
- 06/26/06, CIRB Acknowledgement of No Objection Letter
- 06/23/06, Error in the Schwartz formula conversion to micromolar
- 06/23/06, No Objection Letter for ADVL0524

#### **COG ANBL00B1**

Continuing Review September 2006

Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

#### **COG ANBL0322**

Memo: Fisher Clinical Services transition

Documentation posted:

- 6/9/06, Memo: Fisher Clinical Services transition
- 6/12/06, CIRB Acknowledgement of Receipt

Amendment (Protocol Version 05/22/06)

Documentation posted:

- 4/06/06, Change Memo
- CIRB Application Version 5/22/06
- CIRB Application Version 04/06/06
- 06/14/06: CIRB Acknowledgement of Activation



- 06/09/06: Activation of Amendment
- 06/05/06, CIRB Approval of Protocol (Version dated 5/22/06): Study Chair
- 06/05/06, CIRB Approval of Protocol (Version dated 5/22/06): Local IRB
- 05/25/06: COG Response
- 5/15/06, Approval Pending Modifications (Version dated 5/22/06)
- Protocol Version 5/22/06
- Protocol Version 05/22/06, Highlighted Changes
- Protocol Version 04/06/06
- Informed Consent for Protocol Version 5/22/06
- 05/11/06: Primary Reviewer Comments

Memo: ANBL0322 Eligibility Screen / worksheet  
Documentation Posted:

- 6/16/06, ANBL0322 Eligibility Screen / worksheet
- 6/19/06, CIRB Acknowledgement of ANBL0322 Eligibility Screen/worksheet

Continuing Review September 2006  
Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

#### **COG ANBL0421**

Continuing Review August 2006  
Documentation posted:

- 05/31/06, Continuing Review Notice for August 2006

#### **COG ANHL04B1**

Memo: Coverage for Dr. Termuhlen for ANHL04B1, "Rare and Cutaneous Non-Hodgkin's Lymphoma Registry"  
Documentation Posted:

- 6/16/06, Coverage for Dr. Termuhlen for ANHL04B1, "Rare and Cutaneous Non-Hodgkin's Lymphoma Registry"
- 6/19/06, CIRB Acknowledgement of Coverage for Dr. Termuhlen for ANHL04B1

Continuing Review September 2006  
Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006



### **COG AOST0331**

Memo: Fisher Clinical Services transition

Documentation posted:

- 6/9/06, Memo: Fisher Clinical Services transition
- 6/12/06, CIRB Acknowledgement of Receipt

Continuing Review August 2006

Documentation posted:

- 05/31/06, Continuing Review Notice for August 2006

### **COG ARET0331**

Memo: Revised header for Ophthalmology Review Response forms for ARET0331

Documentation Posted:

- 6/19/06, CIRB Acknowledgement of Revised header for Ophthalmology Review Response forms for ARET0331
- 6/16/06, Revised header for Ophthalmology Review Response forms for ARET0331

### **COG ARET0332**

Continuing Review September 2006

Documentation posted:

- 06/27/06, Continuing Review Notice for September 2006

### **CALGB-100104-ECOG 100104**

Update #3 (Protocol Version 04/03/06)

Documentation posted:

- 05/05/06, Primary Review Comments - Update #3 Review

### **ECOG E1302**

Continuing Review June 2006

Documentation posted:

- Continuing Review June 2006: Group Continuing Review Application
- 6/23/06, Continuing Review June 2006 - Approval (Version dated 12/15/05): Study Chair
- 6/23/06, Continuing Review June 2006 - Approval (Version dated 12/15/05): Local IRB
- 3/7/06, Continuing Review Reminder Notice



- Protocol Version 12/15/05
- Informed Consent for Protocol Version 12/15/05 [Per June 2006 CR]
- June 2006 Group Report

#### **ECOG E2499**

Rituximab Action Letter and Investigator Notification  
Documentation posted:

- 6/09/06, Rituximab Action Letter and Investigator Notification Outcome Letter
- 5/31/06, ECOG Rituximab Memo
- 5/23/06, CAEPR Cover Memo - Rituximab
- 5/23/06, CAEPR Report for Rituximab v1.1
- 5/19/06, IND Action Letter - Rituximab

#### **ECOG E2902**

Addendum #5 (dated 5/25/06)  
Documentation posted:

- 5/25/06, Addendum #5 Change Memo
- 6/16/06, Acknowledgement of Activation
- 6/15/06, ECOG Mailing
- 5/26/06, Approval of May 2006 Continuing Review and Addendum #5 (dated 5/25/06): Study Chair
- 5/26/06, Approval of May 2006 Continuing Review and Addendum #5 (dated 5/25/06): Local IRB
- Protocol Version 5/25/06
- Informed Consent for Protocol Version 5/25/06

#### **GOG 0218**

GOG Informational Memos  
Documentation posted:

- 6/28/06, CIRB Acknowledgement of Receipt
- Memo: Justification for Placebo and Billing for Study Drug
- Memo: Pass Through Mechanism
- Memo: Reimbursement Information

#### **NCCTG N0434**

Continuing Review August 2006  
Documentation posted:

- 06/21/06, Continuing Review Notice for August 2006

#### **NSABP B-33**



Continuing Review June 2006  
Documentation posted:

- Continuing Review June 2006: Group Continuing Review Application
- 6/21/06, Continuing Review June 2006 - Approval (Version dated 03/30/04): Study Chair
- 6/21/06, Continuing Review June 2006 - Approval (Version dated 03/30/04): Local IRB
- 5/26/06, NSABP Cover Letter
- 4/05/06, Notification of Continuing Review 2006
- Protocol, Version 3/30/04 (per Amendment #5)
- Continuing Review June 2006: NSABP Progress Report

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

Memo: Supplemental Funding/CC Credits  
Documentation posted:

- 6/15/06, Acknowledgement of Receipt
- 6/15/06, Memo: Supplemental Funding/CC Credits

Notice of Accrual Closure  
Documentation posted:

- 6/29/06, CIRB Acknowledgement of Receipt
- 6/13/06, Notice of Impending Closure
- 6/01/06, Notice of Impending Closure

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

Amendment #1 (dated 3/30/06)  
Documentation posted:

- 3/30/06, Summary of Protocol and Consent Changes
- Revised CIRB Application (for Protocol Version 3/30/06)
- Summary of CIRB Application Revisions
- 6/21/06, Acknowledgement of Activation
- 5/19/06, Approval to Amendment #1 (Protocol Version 3/30/06): Study Chair
- 5/19/06, Approval to Amendment #1 (Protocol Version 3/30/06): Local IRB
- 3/30/06, NSABP Change Memo
- Protocol, Version 3/30/06
- Informed Consent for Protocol Version 3/30/06
- 5/15/06, Minutes: Amendment #1 Review

#### **NSABP C-08**

Amendment (Protocol Version 4/21/06)



Documentation posted:

- Summary of Changes (per amendment 4/21/06)
- Revised CIRB Application (Protocol Version 4/21/06)
- CIRB Application Summary of Changes (per amendment 4/21/06)
- 6/05/06, Approval of Amendment (dated 4/21/06): Study Chair
- 6/05/06, Approval of Amendment (dated 4/21/06): Local IRB
- Protocol, Version 4/21/06
- Informed Consent Form for Protocol Version 4/21/06

#### **RTOG-0214**

Accrual Challenges Memo

Documentation posted:

- 06/26/06, RTOG Broadcast: Accrual Challenges Memo
- 06/26/06, CIRB Acknowledgement of Receipt

#### **RTOG-0232**

Memo: Clarification of Consent Requirements

Documentation posted:

- 6/16/06, Acknowledgement of Receipt
- 6/15/06, Memo: Clarification of Consent Requirements

Accrual Challenges Memo

Documentation posted:

- 06/26/06, RTOG Broadcast: Accrual Challenges Memo
- 06/26/06, CIRB Acknowledgement of Receipt

#### **RTOG-0320**

Accrual Challenges Memo

Documentation posted:

- 06/26/06, RTOG Broadcast: Accrual Challenges Memo
- 06/26/06, CIRB Acknowledgement of Receipt

#### **RTOG 0412/SWOG S0332**

Accrual Challenges Memo

Documentation posted:

- 06/26/06, RTOG Broadcast: Accrual Challenges Memo
- 06/26/06, CIRB Acknowledgement of Receipt

#### **RTOG-0421**



Accrual Challenges Memo  
Documentation posted:

- 06/26/06, RTOG Broadcast: Accrual Challenges Memo
- 06/26/06, CIRB Acknowledgement of Receipt

**RTOG-0522**

Amendment #1 (dated 06/01/06)  
Documentation posted:

- Amendment #1: Summary of Changes
- Revised CIRB Application (for Protocol Version 6/01/06)
- Summary of CIRB Application Revisions
- 6/21/06, Acknowledgement of Activation
- 6/14/06, Approval for Amendment #1 (Version dated 06/01/06): Study Chair
- 6/14/06, Approval for Amendment #1 (Version dated 06/01/06): Local IRB
- 6/1/06, RTOG Response to CIRB Review
- 5/24/06, Approval Pending Modification to Amendment #1 (dated 4/11/06)
- Protocol, Version 06/01/06
- Informed Consent for Protocol Version 06/01/06
- 05/15/06, Minutes: Amendment #1 Review

**SWOG-S0221**

Memo: Antioxidant Use Questionnaire  
Documentation posted:

- 6/1/06, Memo: Antioxidant Use Questionnaire
- 6/9/06, CIRB Acknowledgement of Protocol Memo

**SWOG-S9910**

Amendment Review: Revision #11 (Protocol Version 02/09/06)  
Documentation Posted:

- CIRB Application Version 02/09/06
- 02/17/06: CIRB Approval (Protocol Version 02/09/06): Study Chair
- 02/17/06: CIRB Approval (Protocol Version 02/09/06): Local IRB
- Protocol Version 02/09/06
- Informed Consent For Protocol Version 02/09/06

**SWOG-S9925**

Revision #9 (dated 2/21/06)  
Documentation Posted:

- Revised CIRB Application (for protocol dated 2/21/06)



- Summary of Changes to CIRB Application
- 02/27/06, Approval to Revision #9 (dated 2/21/06): Study Chair
- 02/27/06, Approval to Revision #9 (dated 2/21/06): Local IRB
- Protocol, Version dated 2/21/06 (includes Revision #9)

Amendment #13 (dated 05/24/06)  
Documentation Posted:

- Revised CIRB Application (for protocol dated 05/24/06)
- Summary of Changes to CIRB Application
- 6/15/06, Acknowledgement of Activation
- 06/09/06, Approval to Amendment #13 (dated 05/24/06): Study Chair
- 06/09/06, Approval to Amendment #13 (dated 05/24/06): Local IRB
- Protocol, Version 05/24/06 (includes Amendment #13)

### **Serious Adverse Events**

**Study: CALGB 100104**

**SAE Posted:**

- 1766366 / lenalidomide
- Lenalidomide-3

**Study: CALGB 10201**

**SAE Posted:**

- AE 1397443 (Follow-up #1)

**Study: CALGB 80203, CALGB 80405**

**SAE Posted:**

- 1842164 / Cetuximab
- Cetuximab 65 / 05-02-06883
- Cetuximab 66 / 05-02-06916
- Cetuximab 67 / 05-02-06321
- Cetuximab 68 / 05-02-06651
- Cetuximab 69 / 05-02-06785
- Cetuximab 70 / 05-02-06619
- Cetuximab 71 / 05-02-06922
- Cetuximab 72 / 06-02-08035
- Cetuximab 73 / 05-02-07391
- Cetuximab 74 / 05-02-07205
- Cetuximab 75 / 06-02-07959

**Study: CALGB 80303, CALGB 80405, CALGB 90206, CALGB 90401**

**SAE Posted:**

- 221942 / bevacizumab-4
- 1663144 / bevacizumab
- 1472508 / bevacizumab



**Study: CALGB 80405**

**SAE Posted:**

-216141 / bevacizumab  
-212109 / bevacizumab-1  
-214919 / bevacizumab-2  
-1389409 / erlotonib and bevacizumab

**Study: CALGB-80405, CALGB-80303, CALGB-90206, CALGB-90401, E1505, E2100, E4599, E5202, E5204, GOG-0218, NSABP-B-40, NSABP-C-08, SWOG S0502**

**SAE Posted:**

-AE 216549

**Study: CALGB-80203, CALGB-80405, NCCTG N0147, SWOG S0205**

**SAE Posted:**

-06-02-07936 / DDL #212

**Study: CALGB-80203, CALGB-80405, RTOG 0522, SWOG S0205**

**SAE Posted:**

-06-02-08451 / DDL #217(1)

**Study: ECOG E1505, ECOG E2100, ECOG E4599, ECOG E5202, ECOG E5204, GOG 0218, NSABP C-08, SWOG S0303, SWOG S0502**

**SAE Posted:**

-1663144  
-1472508

**Study: ECOG E2902**

**SAE Posted:**

-AE 1153342

**Study: ECOG-E2603, ECOG-E2805**

**SAE Posted:**

-AE 1792093

**Study: CALGB 80203, ECOG E3200, ECOG E3201, ECOG E5202, ECOG E6201, NCCTG N0147, NSABP-C-08, NSABP-C-09, SWOG S0303**

**SAE Posted:**

-AE 1086397

**Study: NCCTG N0147**

**SAE Posted:**

-05-02-06295 (Follow-up #3)  
-06-02-08302 / DDL #214 (1)  
-06-02-08451 / DDL #217



-AE 05-02-06295 (Follow-up #4)  
-AE 06-02-08451 / DDL #217 (1)  
-AE 06-02-08501 / DDL #218

**Study: NCIC CTG MA27**

**SAE Posted:**

-2006054771  
-MA27-13-F1

**Study: NSABP C-08**

**SAE Posted:**

-Safety Update #23 / 221942

**Study: RTOG 0320, RTOG 0525**

**SAE Posted:**

-2006-03-1739 (Follow-up #2)  
-2006-04-0529 (Follow-up #2)  
-2006-04-0834 (Follow-up #1)

**Study: RTOG 0522**

**SAE Posted:**

-06-02-07850 / DDL #203 (1)  
-06-02-08216 / DDL #211 (1)  
-06-02-08316 / DDL #216

**Study: SWOG S0124**

**SAE Posted:**

-AE 2006051327(1)  
-AE 2006057230

**Study: SWOG S0205**

**SAE Posted:**

-06-02-08302 / DDL #214(1)  
-06-02-08451 / DDL #217  
-06-02-08501 / DDL #218

**Study: SWOG S0307**

**SAE Posted:**

-AE 2006003410 (1)