



NCI Central IRB Study Activity Update

April 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). 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 or call the CIRB at 888-657-3711.

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 with their request.

****Note:** All documentation can be accessed through the What's New section of the CIRB website (<http://www.ncicirb.org>). ******

Protocol Specific Documentation (listed by protocol)

****Note:** All documentation can be accessed through the Participant's Area (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

CALGB-10603

Initial Review 2008 Approval

Documents Posted:

- Protocol Version 02/05/08
- Protocol Version 11/20/07
- Informed Consent for Protocol 02/05/08
- CIRB Initial Review Application (Protocol Version 02/05/08)
- Summary of CIRB Application Revisions
- CIRB Initial Review Application (Protocol Version 11/20/07)
- 02/22/08: Reviewer 1 Comments
- 02/22/08: Reviewer 3 Comments
- 02/22/08: Reviewer 4 Comments
- 01/04/08: Reviewer 1 Comments
- 01/04/08: Reviewer 2A Comments
- 01/04/08: Reviewer 3 Comments
- 01/04/08: Reviewer 4 Comments
- 03/07/08: CIRB Initial Review Approval February 2008 (Protocol Version 02/05/08)
- 02/05/08: Group Response to CIRB
- 02/04/08: CIRB Table of Initial Review
- 12/05/07: CTEP Approval on Hold
- 11/20/07: Group Response to PIO (RE: Consensus Review)
- 02/22/08: CIRB Meeting Minutes
- 01/04/08: CIRB Meeting Minutes
- 07/06/07: Lab Validation Plan
- 04/30/07: Consensus Review

SWOG-S0777

Initial Review 2008 Approval

Documents Posted:

- Protocol Version 01/10/08
- Protocol Version 10/10/07
- CIRB Initial Review Application (Protocol Version 01/10/08)
- Summary of CIRB Application Revisions (Protocol Version 01/10/08)
- 02/01/08: Reviewer 1 Comments



- 11/19/07: Reviewer 4 Comments (Pharmacist)
- 11/19/07: Reviewer 3 Comments
- 11/19/07: Reviewer 1 Comments
- 02/13/08: CIRB Initial Review Approval February 2008 (Protocol Version 01/10/08)
- 01/10/08: Group Response to CIRB
- 12/11/07: CIRB Table of Initial Review
- 10/23/07: CTEP Approval on Hold
- 02/01/08: CIRB Meeting Minutes
- 11/19/07: CIRB Meeting Minutes
- 09/20/07: Consensus Review
- 07/23/07: Consensus Review
- DSMC- May 2007
- Dosing Principles - October 2004

Other Activity Posted:

CALGB-10501

Amendment Review (AR) Update #1 (Protocol Version Date 02/05/08)

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 02/05/08)
- Summary of CIRB Application Revisions
- 04/09/08: CTEP - Approved as Written Notice
- 04/03/08: CIRB Update #1 Approval March 2008 (Protocol Version 02/05/08)
- Study Summary - Protocol Version 02/05/08
- Protocol Version 02/05/08
- Informed Consent for Protocol Version 02/05/08 [per Up 1]
- 03/17/08: Reviewer Comments
- 03/17/08: CIRB Meeting Minutes

CALGB-40101

Amendment Review (AR) Update #8 (Protocol Version Date 11/08/07)

Documents Posted:

- 12/17/07: Reviewer Comments

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



CALGB-40302

Amendment Review (AR) Update #3 (Protocol Version Date 04/02/08)

Documents Posted:

- CAEPR for Lapatinib
- CIRB Amendment Review Application (Protocol Version 04/02/08)
- Summary of CIRB Application Revisions
- 04/07/08: IND Action Letter
- Glaxo Smith Kline Safety Advisory
- 04/04/08: CIRB Update #3 Approval April 2008 (Protocol Version 04/02/08)
- 04/03/08: Consensus Review
- 04/02/08: Group Response to CTEP
- Status Summary
- Protocol Version 04/02/08
- Informed Consent for Protocol Version 04/02/08 [per Update #3]

CALGB-90206

Amendment Review (AR) Update #9 (Protocol Version Date 08/15/07)

Documents Posted:

- 10/05/07: Reviewer Comments

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

CALGB-SWOG-C80405

Continuing Review (CR) Approval December 2007

Documents Posted:

- 12/07/07: Reviewer Comments

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

CALGB-140503

Amendment Review (AR) Update #2 (Protocol Version Date 02/15/08)

Documents Posted:

- Protocol Update (Protocol Version 02/15/08)
- CIRB Amendment Review Application (Protocol Version 02/15/08)
- Summary of CIRB Application Revisions
- 04/01/08: CIRB Update #2 Approval March 2008 (Protocol Version 02/15/08)
- Protocol Version 02/15/08



- Informed Consent for Protocol Version 02/15/08 [per Up#2]
- 03/17/08: Reviewer Comments
- 03/17/08: CIRB Meeting Minutes

CALGB-140503

Continuing Review (CR) Approval December 2007
Documents Posted:

- 12/07/07: Reviewer Comments

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

COG – AALL06N1

Acknowledgement of Temporary Closure to Accrual (04/03/08)
Documents Posted:

- 04/04/08: CIRB Acknowledgement of Temporary Closure to Accrual
- 04/04/08: AALL06N1 Temporary Closure to Accrual

COG – AAML0523

Acknowledgement of Temporary Closure to Accrual (03/28/08)
Documents Posted:

- 03/31/08: CIRB Acknowledgement of Temporary Closure to Accrual
- 03/28/08: AAML0523 Temporary Closure to Accrual

COG – AAML0531

Amendment Review (AR): Amendment #1 (Protocol Version Date 03/13/08)
Documents Posted:

- CIRB Application (Protocol Version Date 03/13/08)
- CIRB Application (Protocol Version Date 01/23/08)
- CIRB Application (Protocol Version Date 12/13/07)
- CIRB Application (Protocol Version Date 07/19/07)
- 04/04/08: CIRB Approval Amendment #1 February 2008 (Protocol Version Date 03/13/08)
- 03/13/08: Group Change Letter
- 02/29/08: CIRB Approval to Pending Modification of the Group Response to the Amendment Review (Amendment #1)
- 01/23/08: Group Change Letter
- 01/22/08: CIRB Approval to Pending Modification Amendment #1 November 2007 (Protocol Version Date 12/13/07)
- 12/14/07: Group Change Letter



- 12/11/07: CIRB Approval to Pending Modification Amendment #1 November 2007 (Protocol Version Date 07/19/07)
- 07/19/07: Group Change Letter
- Protocol Version 03/13/08
- Protocol Version 03/13/08 - Highlighted Version
- Protocol Version 01/23/08
- Protocol Version 01/23/08 - Highlighted Version
- Protocol Version 12/13/07
- Protocol Version 12/13/07 - Highlighted Version
- Protocol Version 07/19/07
- Protocol Version 07/19/07 - Highlighted Version
- Informed Consent Form for Protocol Version 03/13/08
- Informed Consent Form for Protocol Version 03/13/08 - Additional Bone Marrow
- 02/14/08: Primary Reviewer 1 Comments
- 01/10/08: Primary Reviewer 1 Comments
- 11/08/07: Primary Reviewer 1 Comments
- 02/14/08: Minutes - Group Response to Amendment Review
- 01/10/08: Group Response to Amendment Review
- 11/08/07: Amendment Review

COG – ACCL04C2

Amendment Review (AR) Amendment #2 (Protocol Version Date 2/27/08)
Documents Posted:

- CIRB Application (Protocol Version Date 02/27/08)
- 03/28/08: CIRB Approval Amendment 2 March 2008 (Protocol Version Date 02/27/08)
- 02/27/08: Group Change Letter
- Protocol Version Date 02/27/08
- Protocol Version Date 02/27/08 - Highlighted Version
- Informed Consent Form for Protocol Version Date 02/27/08

COG – ADVL0525

Amendment Review (AR) Amendment #1 (Protocol Version Date 02/13/08)
Documents Posted:

- CIRB Application (Protocol Version Date 02/13/08)
- CIRB Application (Protocol Version Date 12/05/07)
- 03/14/08: CIRB Approval Amendment #1 March 2008 (Protocol Version Date 02/13/08)
- 02/13/08: Group Response to Amendment Review
- 01/21/08: CIRB Approval Pending Modification to Amendment #1 January 2008 (Protocol Version Date 12/05/07)
- 12/14/07: Group Change Letter



- Protocol Version Date 02/13/08
- Protocol Version Date 02/13/08 - Highlighted Version
- Protocol Version Date 12/05/07
- Protocol Version Date 12/05/08 - Highlighted Version
- Informed Consent Form for Protocol Version Date 02/13/08
- 01/10/08: Primary Reviewer 1 Comments
- 01/10/08: Minutes : Amendment Review

COG – ANBL0421

Acknowledgement of Stratum 1 Closure to Enrollment (04/11/08)

Documents Posted:

- 04/11/08: CIRB Acknowledgement of Stratum 1 Closure to Enrollment
- 04/11/08: ANBL0421 Stratum 1 Closure to Enrollment

COG – ASCT0631

Continuing Review (CR) Continuing Review April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/29/07)
- 04/08/08: CIRB Approval to Continuing Review April 2008 (Protocol Version Date 10/29/07)
- 03/06/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/29/07
- Informed Consent Form for Protocol Version Date 10/29/07 - Assent Consent
- Informed Consent Form for Protocol Version Date 10/29/07 - Donor Consent
- Informed Consent Form for Protocol Version Date 10/29/07 - Recipient Consent

ECOG-E1A05

Continuing Review (CR) Approval March 2008

Documents Posted:

- 03/17/08: CIRB Meeting Minutes

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



ECOG-E1899

Continuing Review (CR) Approval October 2007

Documents Posted:

- 10/05/07: Reviewer Comments

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

ECOG-E2603

Continuing Review (CR) Approval April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 11/14/07)
- 04/11/08: CIRB Continuing Review Approval April 2008 (Protocol Version 11/14/07)
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 11/14/07
- Informed Consent for Protocol Version 11/14/07 [per Apr 08 CR]
- 04/04/08: Reviewer Comments
- November-2007: Study Summary
- 09/24/07: DMC Report

ECOG-E2902

Continuing Review (CR) Approval December 2007

Documents Posted:

- 12/07/07: Reviewer Comments

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

ECOG-E4402

Amendment Review (AR) Addendum #4 (Protocol Version Date 08/24/07)

Documents Posted:

- 12/07/07: Reviewer Comments

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



ECOG-E5204

Continuing Review (CR) Approval April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/11/07)
- 04/09/08: CIRB Continuing Review Approval April 2008 (Protocol Version 09/11/07)
- 01/09/08: Continuing Review Notice
- Protocol Version 09/11/07 [per CR 08]
- Informed Consent for Protocol Version 09/11/07 (per Apr 08 CR)
- 04/04/08: Reviewer Comments
- Study Summary - November 2007
- 09/24/07: DMC Recommendations

GOG-0209

Amendment Review (AR) Revision #10 (Protocol Version Date 01/14/08)

Documents Posted:

- 12/07/07: Reviewer Comments

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

NCCTG-N06C6

Amendment Review (AR) Amendment #1 (Protocol Version Date 11/09/07)

Documents Posted:

- 12/07/07: Reviewer Comments

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

NCCTG-N0434 (MA.27D)

Continuing Review (CR) Approval April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/03/07)
- 04/11/08: CIRB Continuing Review Approval April 2008 (Protocol Version 07/03/07)
- 01/09/08: Continuing Review Notice
- Protocol Version 07/03/07
- Protocol Version 07/03/07 (Administrative & Editorial Changes)



- Informed Consent for Protocol Version 07/03/07 [per Apr 08 CR]
- 04/04/08: Reviewer Comments

NCCTG-N0574

Amendment Review (AR) Addendum #2 (Protocol Version Date 08/29/07)
Documents Posted:

- 10/05/07: Reviewer Comments

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

NCIC-CTG-MA.27

Continuing Review (CR) Approval April 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/02/07)
- 04/11/08: CIRB Continuing Review Approval April 2008 (Protocol Version 05/02/07)
- 02/26/08: Continuing Review Notice
- Protocol Version 05/02/07 [Non-Companion]
- Informed Consent for Protocol Version 05/02/07 [per Apr 08 CR]
- 04/04/08: Reviewer Comments
- 10/20/07: DSMB Summary
- 2007 - ASCO Symposium
- Study Summary
- SAE Report

NCIC-CTG-PR.11

Continuing Review (CR) Approval December 2007
Documents Posted:

- 12/07/07: Reviewer Comments

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

NSABP-B-40

Continuing Review (CR) Approval December 2007
Documents Posted:

- 12/17/07: Reviewer Comments

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



RTOG-0232

Amendment Review (AR) Amendment #4 (Protocol Version Date 01/11/08)
Documents Posted:

- Summary of Changes-Protocol Version 01/11/08
- CIRB Amendment Review Application (Protocol Version 01/11/08)
- Summary of CIRB Application Revisions
- 02/25/08: CIRB Amendment 4 Approval February 2008 Protocol Version 01/11/08
- 01/16/08: CTEP Memo
- 01/14/08: CTEP-PIO Recommendation
- 01/11/08: Group Cover Letter
- Protocol Version 01/11/08
- Protocol Version 01/11/08 (Track Changes)
- Informed Consent for Protocol Version 01/11/08 [per Am 4]
- 02/22/08: Reviewer 1 Comments
- 02/22/08: Reviewer 2 Comments
- 02/22/08: Reviewer 3 Comments
- 02/22/08: CIRB Meeting Minutes

Continuing Review (CR) Approval December 2007
Documents Posted:

- 12/07/07: Reviewer Comments

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

RTOG-0617

Continuing Review (CR) Approval March 2008
Documents Posted:

- 03/17/08: CIRB Meeting Minutes

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

SWOG-S0124

Continuing Review (CR) Approval March 2008
Documents Posted:

- 03/17/08: CIRB Meeting Minutes

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



SWOG-S0307

Continuing Review (CR) Approval April 2008

Documents Posted:

- CIRB Continuing Review Application
- 04/11/08: CIRB Continuing Review Approval April 2008 (Protocol Version 06/18/07)
- 01/09/08: CIRB Continuing Review Notice
- Protocol Version 06/18/07
- Informed Consent for Protocol Version 06/18/07 [per Apr 08 CR]
- 04/04/08: Reviewer Comments
- Study Summary - May 2008
- 03/12/08: SAE Report
- 10/11/07: DSMC Memo

SWOG-S0600

Continuing Review (CR) Approval April 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 09/27/07)
- 04/09/08: CIRB Continuing Review Approval April 2008 Protocol Version 09/27/07
- 01/09/08: CIRB Continuing Review Notice
- 10/11/07: Group DSMC Memo (Minutes)
- Protocol Version 09/27/07
- Informed Consent for Protocol Version 09/27/07 [per CR Apr 08]
- 04/04/08: Reviewer Comments

SWOG-S0600

Amendment Review (AR) Amendment #1 (Protocol Version Date 09/27/07)

Documents Posted:

- 12/07/07: Reviewer Comments

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

SWOG-S0777

Amendment Review (AR) Activation Amendment (Revision #5) (Protocol Version Date 02/28/08)

Documents Posted:

- CIRB Amendment Review Application (Protocol Version 02/28/08)
- Summary of CIRB Application Revisions



- 03/04/08: CIRB Revision #5 Approval February 2008 Protocol Version 02/28/08
- 02/29/08: CTEP Approval on Hold
- 02/28/08: Group Response to PIO
- Protocol Version 02/28/08
- Informed Consent for Protocol Version 02/28/08 [per Rev5]

Serious Adverse Events

Study: ADVL 0525

SAE Posted: US200710006846, ES200709003440, CA200711000761, DE031212518, US200707001194, BE200710004138, DE200710003454, HU200710007592

Study: CALGB 80203

SAE Posted: 144051, 1609725, 07-02-13577(1), 1435303

Study: CALGB 80303

SAE Posted: 250945, 1435303, 1459647

Study: CALGB 90206

SAE Posted: 1435303, 1459647

Study: CALGB 90401

SAE Posted: 250945, 1435303, 1459647

Study: ECOG E1105

SAE Posted: 250945, 1435303, 1459647

Study: ECOG E1305

SAE Posted: 250945, 1435303, 1459647

Study: ECOG E1505

SAE Posted: 250945, 1435303, 1459647

Study: ECOG E2100

SAE Posted: 250945, 1435303, 1459647

Study: ECOG E3201

SAE Posted: 1609725, 144051

Study: ECOG E4599

SAE Posted: 250945, 1435303, 1459647



Study: ECOG E5103
SAE Posted: 250945, 1435303, 1459647

Study: ECOG E5202
SAE Posted: 144051, 250945, 1609725, 1435303, 1459647

Study: ECOG5204
SAE Posted: 144051, 250945, 1609725, 1435303, 1459647

Study: ECOG E6201
SAE Posted: 144051, 1609725

Study: GOG 0213
SAE Posted: 250945, 1435303, 1459647

Study: GOG 0218
SAE Posted: 250945,1435303, 1459647

Study: NCCTG N0147
SAE Posted: 144051, 1609725, 07-02-13577(1) ,1435303

Study: NSABP C-08
SAE Posted: 144051, 1609725

Study: NSABP C-09
SAE Posted: 144051, 1609725

Study: NSABP R-04
SAE Posted: 144051, 1609725

Study: NSABP B-40
SAE Posted: 250866(3), 250868(3), 250945(1), 252388(4), 253089(2), 253192(1), 254176, 255141, 1435303, 1459647

Study: NSABP C-08
SAE Posted: 250866(3), 250868(3), 250945(1), 252388(4), 253089(2), 253192(1), 254176, 255141, 1435303, 1459647

Study: NSABPB-34
SAE Posted: 200812652 Safety Update #72, 200812671 Safety Update #74, 200813174 Safety Update #74

Study: RTOG 0522
SAE Posted: 07-02-13171, 08-02-13772, 08-02-13725, 07-02-13171(1) , 1435303

Study: RTOG 0436



SAE Posted: 07-02-13577(1), 1435303

Study: SWOG S0502

SAE Posted: 250945, 1435303, 1459647

Study: SWOG S0518

SAE Posted: 250945, 1435303, 1459647

Study: SWOG S0600

SAE Posted: 250945, 07-02-13577(1), 1435303, 1459647

Corrections to Previous Study Activity Updates

SWOG-S0221

Amendment Review Amendment #5 Approval February 2008

Documents Posted:

04/02/08: ERRATUM - Amendment #5 Approval

Informed Consent for Protocol Version Date 01/01/08 (per Am 5)

Correction:

The information regarding changes to the informed consent for the approval letter dated February 22, 2008 should read: "Amendment #5 did involve changes to the informed consent form."

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.