



NCI Central IRB Study Activity Update June 30, 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). 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

NCIC CTG – PR.11

Initial Review 2007

Documents Posted:

- Protocol Version Date 05/18/07
- Protocol Version Date 04/05/05
- Informed Consent Form for Protocol Version Date 05/18/07
- CIRB Application (Protocol Version Date 05/18/07)
- 02/02/07: Primary Reviewer 1 Comments
- 02/02/07: Primary Reviewer 2 Comments
- 05/24/07: CIRB Final Approval
- 05/14/07: CIRB Table of the Recruitment Video
- 05/14/07: CIRB APM of the Group Response to the Initial Review
- 04/05/07: Group Response
- 03/21/07: CIRB Approval Pending Modification
- 04/16/07: Minutes: Group Response to Initial Review
- 02/02/07: Minutes: Initial Review

SWOG - S0600

Initial Review 2006

Documents Posted:

- Protocol Version Date 12/13/06
- Protocol Version Date 07/10/06
- Informed Consent Form for Protocol Version Date 12/13/06
- Summary of CIRB Application Revisions (Protocol Version Date 12/13/06)
- CIRB Application (Protocol Version Date 12/13/06)
- CIRB Application (Protocol Version Date 07/10/06)
- 01/22/07: Primary Reviewer 1 Comments
- 01/05/07: Primary Reviewer 1 Comments
- 01/05/07: Primary Reviewer 2 Comments
- 01/24/07: Approval Letter
- 12/13/06: Group Response Letter
- 08/21/06: CIRB Approval Pending Modification



Other Activity Posted:

CALGB 100104

Amendment Review (AR): Update #5
Documents Posted:

- 03/19/07: Primary Reviewer 1 Comments

CALGB- 10201

Continuing Review (CR) February 2007
Documents Posted:

- 02/12/07: Primary Reviewer 1 Comments
- 02/12/07: Minutes: Continuing Review

CALGB 49907

Amendment Review (AR): Update #15
Documents Posted:

- 03/02/07: Primary Reviewer 1 Comments
- 03/02/07: Minutes: Amendment Review

Continuing Review (CR) June 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/31/07)
- 06/05/07: Approval Letter
- Protocol Version Date 01/31/07
- Study Summary

CALGB 50303

Amendment Review (AR): Update #4
Documents Posted:

- 02/02/07: Primary Reviewer 1 Comments
- 02/02/07: Minutes: Amendment Review

CALGB 70301

Continuing Review (CR) January 2007
Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments



CALGB 80203

Amendment Review (AR): Update #5
Documents Posted:

- 04/06/07: Primary Reviewer 1 Comments

CALGB – SWOG – C80405

Continuing Review (CR) February 2007
Documents Posted:

- 02/02/07: Primary Reviewer 1 Comments
- 02/02/07: Minutes: Continuing Review

CALGB 90206

Amendment Review (AR): Amendment #8
Documents Posted:

- 06/11/07: Approval Letter
- Protocol Version Date 03/26/07

COG – AAML0523

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

- 12/28/06: Primary Reviewer 1 Comments
- 12/28/06: Amendment Review Minutes
- Protocol Version Date 10/27/06
- Protocol Version Date 10/27/06 Highlighted
- 02/08/07: Group Response Minutes
- 12/28/06: Amendment Review Minutes
- CIRB Application Protocol Version Date 10/27/06

COG – AAML06P1

Initial Review 2006
Documents Posted:

- 02/05/07: Primary Reviewer 1 Comments
- 02/08/07: Group Response Initial Review Meeting Minutes

COG – ACNS0222

Amendment Review (AR) CIRB Acknowledgement of Memo re: Activation of AALL05B1.
Documents Posted:

- 04/12/07: Primary Reviewer 1



- 04/12/07: Amendment Review Minutes

COG – ABTR04B1

Amendment Review (AR) Amendment #2

Documents Posted:

- 01/10/07: Primary Reviewer 1 Comments
- 01/11/07: Amendment Review Minutes

COG – AEWS0621

Initial Review 2006

Documents Posted:

- 02/07/07: Primary Reviewer 1 Comments
- 02/08/07: Group Response to Initial Review Minutes

COG – AHOD03P1

Amendment Review (AR) Amendment #2

Documents Posted:

- 12/28/06: Primary Reviewer 1 Comments
- 12/28/06: Amendment Review Minutes

COG – AHOD04B1

Continuing Review (CR) May 2007

Documents Posted:

- 04/06/07: Primary Reviewer 1
- 04/12/07: Continuing Review Minutes

COG – AHOD0521

Continuing Review (CR) May 2007

Documents Posted:

- 04/06/07: Primary Reviewer 1

COG – AREN0532

Continuing Review (CR) January 2007

Documents Posted:

- 01/09/07: Primary Reviewer 1 Comments
- 01/11/07: Continuing Review Minutes



COG – ASCT0431

Initial Review 2006
Documents Posted:

- 12/14/06: Primary Reviewer 1 Comments

COG – D9902

Amendment Review #9 (Protocol Version Date 04/02/07)
Documents Posted:

- 03/21/07: Primary Reviewer 1 Comments
- 03/22/07: Amendment Review Minutes

ECOG – E1A00

Continuing Review (CR) January 2007
Documents Posted:

- 01/22/07: Primary Reviewer 1 Comments

ECOG – E1Y03

Continuing Review (CR) November 2006
Documents Posted:

- 03/19/07: Primary Reviewer 1 Comments

ECOG – E1302

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

- 01/05/07: Primary Reviewer 1 Comments

Continuing Review (CR) April 2007
Documents Posted:

- 04/16/07: Primary Reviewer 1 Comments
- 04/16/07: Minutes: Continuing Review

ECOG – E2603

Amendment Review (AR): Addendum #8
Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments



ECOG – E2902

Continuing Review (CR) February 2007

Documents Posted:

- 02/12/07: Primary Reviewer 1 Comments
- 02/12/07: Minutes: Continuing Review

ECOG – E4201

Continuing Review (CR) January 2007

Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments

ECOG – E5202

Continuing Review (CR) March 2007

Documents Posted:

- 03/02/07: Primary Reviewer 1 Comments
- 03/02/07: Minutes: Continuing Review

GOG – 0209

Amendment Review (AR): Revision #9

Documents Posted:

- 02/02/07: Primary Reviewer 1 Comments
- 02/02/07: Minutes: Amendment Review

GOG – 0218

Continuing Review (CR) January 2007

Documents Posted:

- 01/22/07: Primary Reviewer 1 Comments

GOG – 0219

Amendment Review (AR): Revision #4

Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments

NCIC CTG – MA.27

Amendment Review (AR): Amendment #5A

Documents Posted:

- Summary of CIRB Application Revisions
- Summary of Protocol Changes
- CIRB Application (Protocol Version Date 11/03/06)



- 03/01/07: Approval Letter
- Protocol Version Date 11/03/06 [Non-Companion]
- Informed Consent Form for Protocol Version Date 11/03/06 [Non-Companion]
- 02/02/07: Primary Reviewer 1 Comments
- 02/02/07: Minutes: Amendment Review

NSABP – B - 33

Continuing Review (CR) April 2007

Documents Posted:

- 04/06/07: Primary Reviewer 1 Comments
- 04/06/07: Minutes: Continuing Review

NSABP – B - 34

Continuing Review (CR) January 2007

Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments

NSABP – B - 35

Continuing Review (CR) January 2007

Documents Posted:

- 01/22/07: Primary Reviewer 1 Comments

NSABP – B – 39/RTOG - 0413

Amendment Review (AR): Amendment #2

Documents Posted:

- 02/12/07: Primary Reviewer 1 Comments

Continuing Review (CR) January 2007

Documents Posted:

- 03/19/07: Primary Reviewer 1 Comments
- 03/19/07: Minutes: Continuing Review

NSABP – B - 42

Continuing Review (CR) January 2007

Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments



NSABP – R - 04

Continuing Review (CR) May 2007

Documents Posted:

- 03/19/07: Primary Reviewer 1 Comments
- 03/19/07: Minutes: Continuing Review

RTOG - 0126

Continuing Review (CR) January 2007

Documents Posted:

- 01/22/07: Primary Reviewer 1 Comments

RTOG - 0214

Continuing Review (CR) January 2007

Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments

RTOG - 0232

Continuing Review (CR) February 2007

Documents Posted:

- 02/12/07: Primary Reviewer 1 Comments
- 02/12/07: Minutes: Continuing Review

RTOG - 0320

Amendment Review (AR): Amendment #4

Documents Posted:

- 04/06/07: Primary Reviewer 1 Comments

RTOG - 0521

Continuing Review (CR) March 2007

Documents Posted:

- 03/02/07: Primary Reviewer 1 Comments
- 03/02/07: Minutes: Continuing Review

SWOG - S0106

Amendment Review (AR): Revision #5

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 05/02/07)
- 05/22/07: Approval Letter



- Protocol Version Date 05/02/07
- Informed Consent Form for Protocol Version Date 05/02/07

SWOG - S0200

Amendment Review (AR): Revision #5
Documents Posted:

- 06/06/07: Approval Letter
- Protocol Version Date 02/21/07

SWOG - S0205

Continuing Review (CR) January 2007
Documents Posted:

- 01/22/07: Primary Reviewer 1 Comments

SWOG - S0232

Continuing Review (CR) January 2007
Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments

SWOG - S0307

Amendment Review (AR): Revision #3
Documents Posted:

- 03/19/07: Primary Reviewer 1 Comments
- 03/19/07: Minutes: Amendment Review

SWOG - S0309

Amendment Review (AR): Revision #7
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 02/12/07)
- 04/19/07: Approval Letter
- Protocol Version Date 02/12/07

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

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 02/27/06)
- 03/09/06: Approval Letter
- Protocol Version Date 02/27/06



SWOG - S0421

Continuing Review (CR) January 2007
Documents Posted:

- 01/05/07: Primary Reviewer 1 Comments

SWOG - S0427

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

- 01/22/07: Primary Reviewer 1 Comments

SWOG - S0500

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

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 05/15/07)
- 06/06/07: Approval Letter
- Protocol Version Date 05/15/07
- Informed Consent Form for Protocol Version Date 05/15/07

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

- 01/05/07: Primary Reviewer 1 Comments

SWOG - S0521

Initial Review 2006
Documents Posted:

- 03/19/07: Primary Reviewer 1 Comments
- 03/19/07: Primary Reviewer 2 Comments

SWOG - S0600

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

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 03/05/07)
- 05/09/07: Approval Letter
- 05/07/07: Group Response Letter
- 05/03/07: CIRB Approval Pending Modification
- 03/05/07: Group Response Letter



- Protocol Version Date 05/07/07
- Protocol Version Date 03/05/07
- Informed Consent Form for Protocol Version Date 05/07/07
- 04/06/07: Primary Reviewer 1 Comments
- 04/06/07: Minutes - Amendment Review

Continuing Review (CR) May 2007
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/07/07)
- 05/22/07: Approval Letter
- Protocol Version Date 05/07/07
- Informed Consent Form for Protocol Version Date 05/07/07

Serious Adverse Events

Study: CALGB-80303
SAEs Posted: 232653 (4), 236972

Study: CALGB-90206
SAEs Posted: 232653 (4), 236972

Study: CALGB-90401
SAEs Posted: 232653 (4), 236972

Study: CALGB-SWOG-80405
SAEs Posted: 232653 (4), 236972

Study: ECOG E2100
SAEs Posted: 232653 (4), 236972

Study: ECOG E2603
SAE Posted: 1893074

Study: ECOG E2805
SAE Posted: 1893074, 2007006307

Study: ECOG E3200
SAEs Posted: 232653 (4), 236972

Study: ECOG E4599
SAEs Posted: 232653 (4), 236972



Study: ECOG E5202
SAEs Posted: 232653 (4), 236972

Study: ECOG E5204
SAEs Posted: 232653 (4), 236972

Study: GOG-0212
SAE Posted: PGT-04-0283 (0)

Study: GOG-0218
SAEs Posted: 232653 (4), 236972

Study: NCIC CTG MA.27
SAE Posted: MA27-17

Study: NSABP B-40
SAEs Posted: 232344 (2), 232653 (4), 235241 (2), 235298 (1), 235492, 235611, 236250, 236250 (1), 236761, 236761 (1), 236972, 237588, 238168, 238168 (1)

Study: NSABP C-08
SAEs Posted: 232653 (4), 235492, 235611, 236972, 236972 (1)

Study: RTOG 0320
SAEs Posted: 2007SP003140, 2007SP003140 (1), 2007SP003140 (5)

Study: RTOG-0522
SAEs Posted: DDL 244 (1) / 07-02-11206, DDL 249 / 07-02-11728

Study: RTOG 0525
SAEs Posted: 2007SP003140, 2007SP003140 (1), 2007SP003140 (5)

Study: SWOG S0205
SAEs Posted: DDL 244 (1) / 07-02-11206, DDL 248 / 07-02-11537

Study: SWOG S0303
SAEs Posted: 232653 (4), 236972



Corrections to Previous Study Activity Updates

COG- ACNS0332

This Amendment Review included in the June 15, 2007 Study Activity Update should have been designated Amendment #2 for COG-ANBL0322. Please note for COG-ACNS0332 only the activation amendment is available.

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.