



NCI Central IRB Study Activity Update December 14, 2007

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 S0518

Initial Review 2007 Approval
Documents Posted:

- Protocol Version 09/04/07
- Protocol Version 07/25/07
- Protocol Version 02/01/07
- Protocol Version 07/28/06
- Informed Consent for Protocol Version 09/04/07
- CIRB Initial Review Application (Protocol Version 09/04/07)
- Summary of CIRB Application Revisions (Protocol Version 09/04/07)
- CIRB Initial Review Application (Protocol Version 07/25/07)
- Summary of CIRB Application Revisions (Protocol Version 07/25/07)
- CIRB Initial Review Application (Protocol Version 02/01/07)
- Summary of CIRB Application Revisions (Protocol Version 02/01/07)
- CIRB Initial Review Application (Protocol Version 07/28/06)
- 10/15/07: CIRB Final Approval Initial Review October 2007 (Protocol Version 09/04/07)
- 10/08/07: CIRB Approval Pending Modification of Group Response (Protocol Version 09/04/07)
- 09/05/07: CTEP Approval on Hold Approval (Protocol Version 09/04/07)
- 09/04/07: Group Response Letter
- 09/04/07: CTEP-PIO Memo (Protocol Version 09/04/07)
- 09/04/07: CTEP Approval of Changes (Protocol Version 09/04/07)
- 07/27/07: Group Response Letter
- 04/06/07: CIRB Approval Pending Modification (Protocol Version 02/01/07)
- 02/12/07: Group Response to CIRB
- 09/06/06: CIRB Approval Pending Modification (Protocol Version 07/28/06)
- 08/31/06: CIRB Approval Pending Modifications (Protocol Version 07/28/06)
- 07/28/06: Group Change Letter
- No Date: CTEP Approval on Hold (Protocol Version 07/28/06)



- 09/07/07: Minutes: Group Response to Initial Review
- 03/19/07: Minutes: Group Response to Initial Review
- 08/21/06: Minutes: Group Response to Initial Review

Other Activity Posted:

CALGB 70301

Continuing Review (CR) November 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/4/07)
- CIRB Continuing Review Approval Pending Modification November 2007 (Protocol Version 01/24/07)
- Protocol Version Date 01/24/07
- Informed Consent for Protocol Version 01/24/07 [per Nov 07 CR]

CALGB 90206

Amendment Review (AR) Update #9
Documents Posted:

- Summary of Changes
- 10/31/07: CIRB Approval Letter Update #9 October 2007 (Protocol Version 08/15/07)
- Protocol Version Date 08/15/07

CALGB 140503

Amendment Review (AR) July 2007 Update #1
Documents Posted:

- Summary of CIRB Application Revisions
- Protocol Update
- CIRB Review Application (Protocol Version Date 06/15/07)
- 07/27/07: CIRB Amendment Approval July 2007 (Protocol Version Date 06/15/07)
- Protocol Version Date 06/15/07 Includes Update #1
- Informed Consent for Protocol Version 06/15/07 [per Update 1]



COG – AEWS0621

Amendment Review (AR) Amendment #1
Documents Posted:

- CIRB Application (Protocol Version Date 11/06/07)
- 11/21/07: CIRB Approval Amendment #1 (Protocol Version Date 11/06/07)
- 11/06/07: Change Letter
- Protocol Version Date 11/06/07
- Protocol Version Date 11/06/07 - Highlighted Version
- Informed Consent Form for Protocol Version Date 11/06/07

COG – AREN0532

Continuing Review (CR) November 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 10/16/07)
- 12/07/07: CIRB Continuing Review Approval (Protocol Version 10/16/07)
- Protocol Version 10/16/07 [per Nov 07 CR]
- Informed Consent for Protocol Version 10/16/07: Chemotherapy Arm
- Informed Consent for Protocol Version 10/16/07: Observation Arm
- Study Summary Fall 2007

GOG 0209

Continuing Review (CR) November 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 12/18/06)
- 12/03/07: CIRB Continuing Review Approval November 2007 (12/18/06)
- Protocol Version 12/18/06
- Informed Consent for Protocol Version 12/18/06 [per Nov 07 CR]
- Study Summary July 2007
- 07/21/07: DSMB Minutes

ECOG E2603

Amendment Review (AR) December 2007 Update #4
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version 11/14/07)
- 12/10/07: CIRB Update #4 Approval Dec 2007 (Protocol Version 11/14/07)
- Protocol Version 11/14/07
- Informed Consent Form for Protocol Version Date 11/14/07



ECOG PACCT-1

Amendment Review (AR) December 2007 Amendment #5

Documents Posted:

- Summary of CIRB Application Revisions-Protocol Version Date 11/14/07
- CIRB Application (Protocol Version 11/14/07)
- 12/11/07: CIRB Amendment #5 Approval December 2007 (Protocol Version 11/14/07)
- 11/14/07: Group Letter to CTEP
- Protocol Version 11/14/07
- Informed Consent form for Protocol Version 11/14/07 [per Am 5 Dec 07]

NCCTG-N0574

Amendment Review (AR) October 2007 Addendum #2

Documents Posted:

- Summary of Application Revisions
- CIRB Application (Protocol Version Date 08/29/07)
- 11/08/07: CIRB Addendum 2 Approval October 2007 (Protocol Version 08/29/07)
- Protocol Version 08/29/07 [per Add2 Oct 07]
- Informed Consent for Protocol Version 08/29/07 [per Add 2 Oct 07]

NSABP B-34

Continuing Review (CR) November 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/19/07)
- 11/30/07: CIRB Continuing Review Approval November 2007 (Protocol Version 04/19/07)
- 10/12/07: Group Letter
- Protocol Version 04/19/07
- 04/13/07: DMC Minutes
- Study Summary

NSABP B-35

Continuing Review (CR) November 2007 Approval

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/26/07)
- 12/03/07: CIRB Continuing Review Approval November 2007 (Protocol Version 03/26/07)
- 10/29/07: Group Cover Letter



- Protocol Version 03/26/07
- 10/12/07: DMC Minutes
- 04/13/07: DMC Minutes
- Study Progress Report

NSABP B-42

Continuing Review (CR) November 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/12/06)
- 11/30/07: CIRB Continuing Review Approval Pending Modification Nov 2007 (Protocol Version 07/12/06)
- 10/12/07: Group Letter
- Protocol Version 07/12/06
- Informed Consent for Protocol Version 07/12/06 [per Nov 07 CR]: Main Study
- Study Summary

RTOG 0126

Continuing Review (CR) November 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/19/07)
- 11/30/07: CIRB Continuing Review Approval November 2007 (Protocol Version 09/19/07)
- Protocol Version 09/19/07
- Informed Consent for Protocol Version 09/19/07 [per Nov 07 CR]
- Informed Consent for Protocol Version Date 09/19/07 [Tissue Consent]
- Summary of Changes
- Study Summary June 2007
- Dearnaley Article
- Peeters Dutch Article
- Pollack Article
- Zeitman Article

SWOG S0421

Continuing Review (CR) November 2007 Approval
Documents Posted:

- CIRB Continuing Review Application (Protocol Version 02/01/07)
- 12/11/07: CIRB Continuing Review Approval November 2007 (Protocol Version 02/01/07)
- Protocol Version 02/01/07
- Informed Consent for Protocol Version 02/01/07 [per Nov 07 CR]
- Report of Studies October 2007



Serious Adverse Events

Study: **Study Number**
SAE Posted:

Corrections to Previous Study Activity Updates

CALGB 80203

Continuing Review August 2007 Approval
Documents Posted:

- 11/28/07: ERRATUM: CIRB Approval Expiration Date

Correction:

The CALGB 80203 continuing review approval letter dated August 20, 2007 contains an error in the expiration date. The date should read "August 1, 2008" instead of "August 2, 2008."

CALGB 90401

Notice of Closure to Accrual Acknowledgement of Submission
Documents Posted:

- 11/28/07: CIRB Acknowledgement of Receipt (Closure to Accrual)

Correction:

- The Study Number was added with this correction.

SWOG S0307

Revision to Informed Consent for Amendment 1
Documents Posted:

- Informed Consent for Protocol Version 06/18/07 (revised)

Correction:

Formatting for Informed Consent was corrected.



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.