



NCI Central IRB Study Activity Update December 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). 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.

Pediatric CIRB Studies

COG-ACCRN07

Initial Review 2007 Approval
Documents Posted:

- Protocol Version Date 09/19/07
- Protocol Version Date 09/19/07 Highlighted Version
- Protocol Version Date 07/19/07
- Protocol Version Date 07/19/07 Highlighted Version
- Protocol Version Date 05/03/07
- Protocol Version Date 05/03/07 Highlighted Version
- Protocol Version Date 02/05/07
- Informed Consent for Protocol Version Date 09/19/07
- CIRB Application (Protocol Version Date 09/19/07)
- CIRB Application (Protocol Version Date 07/19/07)
- CIRB Application (Protocol Version Date 05/03/07)
- CIRB Application (Protocol Version Date 02/05/07)
- 06/14/07: Primary Reviewer 1
- 09/21/07: CIRB Final Approval (Protocol Version Date 09/19/07)
- 09/19/07: Group Response Letter
- 09/17/07: CIRB Approval Pending Modification (Protocol Version Date 07/19/07)
- 07/19/07: Group Response Letter
- 06/22/07: CIRB Table of the Group Response to the Initial Review
- 05/03/07: Group Response Tabled Letter
- 03/29/07: CIRB Table of Initial Review
- 02/05/07: Change Memo
- 06/14/07: Group Response to Initial Tabled Review



Other Activity Posted:

CALGB-100104 ECOG 100104

Amendment Review Update #6 Approval

Documents Posted:

- 06/15/07: Protocol Revisions Update
- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 06/11/07)
- 09/18/07: CIRB Update #6 Approval September 2007 (Protocol Version 06/11/07)
- Protocol Version 06/11/07 [includes update 6]
- Informed Consent Form for Protocol Version 06/11/07 [per update 6]

COG-AAML0523

Continuing Review (CR): November 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/12/07)
- 12/14/07: CIRB Continuing Review Approval Letter (Protocol Version Date 01/12/07)
- 12/13/07: Group Response to Approval Pending Modifications
- 12/11/07: CIRB Approval Pending Modifications Letter
- Protocol Version Date 01/12/07
- Informed Consent Form for Protocol Version Date 01/12/07 [per Nov 07 CR]

COG-ACNS0224

Closure to Accrual: December 2007

Documents Posted:

- 12/28/07: COG Permanent Closure Letter
- 12/28/07: CIRB Acknowledgement of Study Closure

ECOG-E5103

Amendment Review Amendment #2 Approval

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version 11/02/07)
- 11/26/07: CIRB Amendment 2 Approval November 2007 Protocol Version 11/02/07
- 11/02/07: Group Cover Letter



- Protocol Version 11/02/07
- Informed Consent Form for Protocol Version 11/02/07

GOG-0218

Continuing Review (CR) November 2007 Approval

Documents Posted:

- CIRB Continuing Review Application
- 12/11/07: CIRB Continuing Review Approval November 2007 (Protocol Version 07/13/07)
- Protocol Version Date 07/13/07
- Appendix I
- Appendix II
- Appendix III
- Appendix IV
- Appendix V
- Appendix VI
- Appendix VII
- Appendix VIII
- Informed Consent for Protocol Version 07/13/07 [per Nov 2007 CR]
- Status Report
- Investigator's Drug Brochure V.13 October 2005

NCCTG-N0147

Amendment Review Addendum #7 Approval

Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version Date 10/08/07)
- 12/11/07: CIRB Addendum #7 Approval November 2007 (Protocol Version 10/08/07)
- Protocol Version Date 10/08/07 [per Addendum #7]
- Informed Consent Form for Protocol Version 10/08/07 [per Addendum #7]

NSABP-B-42

Amendment Review Amendment #1 Approval

Documents Posted:

- 06/05/07: Group Change Memo
- 05/30/07: Summary of Changes
- Summary of CIRB Application Revisions (Protocol Version 05/30/07)
- CIRB Application Protocol Version 05/30/07
- 06/21/07: CIRB Amendment 1 Approval June 2007 (Protocol Version 05/30/07)
- Protocol Version 05/30/07



- Informed Consent for Protocol Version 05/30/07: Main Study
- Informed Consent for Protocol Version 05/30/07: Registration Program

Amendment Review Amendment #2 Approval
Documents Posted:

- 09/21/07: Group Change Memo
- 09/12/07: Summary of Changes
- Summary of CIRB Application Revisions (Protocol Version 09/12/07)
- CIRB Application Protocol Version 09/12/07
- 10/03/07: CIRB Amendment 2 Approval October 2007 (Protocol Version 09/2/07)
- Protocol Version 09/12/07
- Informed Consent for Protocol Version 09/12/07 [per Amendment 2]: Main Study
- Informed Consent for Protocol Version 09/12/07 [per Amendment 2]: Registration Program

SWOG-S9910

Amendment Review Revision #14 Approval
Documents Posted:

- Summary of CIRB Application Revisions
- CIRB Application (Protocol Version 08/27/07)
- 09/19/07: CIRB Revision 14 Approval September 2007 (Protocol Version 08/27/07)
- Protocol Version 08/27/07 [per Revision 14]
- Informed Consent Form for Protocol Version Date 08/27/07 [per Revision 14]

Corrections to Previous Study Activity Updates

CALGB-70301

- 12/20/07:ERRATUM: CIRB Subject Line for Continuing Review Approval

CALGB-80203

- 12/18/07: ERRATUM: CIRB Approval Expiration Date (Revised)



CALGB-90206

- 12/20/07: ERRATUM: CIRB Approval Expiration Date for Continuing Review (Protocol Version 03/26/07)
- 12/20/07: ERRATUM: CIRB Review of Update #9

RTOG-0126

- 12/20/07: ERRATUM: CIRB Subject Line for Continuing Review Approval

If you have any questions about the CIRB Initiative, please contact the CIRB at ncicirbcontact@emmes.com.