



NCI Central IRB Study Activity Update September 15, 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 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@ctisinc.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@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>). **

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

ECOG-E3805

Initial Review Approval
Documentation posted:

- Protocol Version 06/02/05
- Protocol Version 09/26/05
- Informed Consent for Protocol Version 09/26/05
- CIRB Application Version 06/02/05
- Summary of CIRB Application Revisions Version 09/26/05
- CIRB Application Version 09/26/05
- 07/15/05: Primary Reviewer 1 Comments
- 07/18/05: Primary Reviewer 2 Comments
- 06/02/05: ECOG Response to CTEP Review
- 10/27/05: CIRB Approval (Protocol Version 09/26/05): Study Chair
- 10/27/05: CIRB Approval (Protocol Version 09/26/05): Local IRB
- 09/26/05: ECOG Response to Approval Pending Modification
- 08/11/05: Approval Pending Modification (Protocol Version 06/02/05)
- 07/18/05: Initial Review Meeting Minutes

Other Activity Posted:

COG-AALL03B1

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page
Documentation posted:

- 09/11/06: CIRB Acknowledgement of Classification of Acute Lymphoblastic Leukemia
- 09/08/06: Memo of Classification of Acute Lymphoblastic Leukemia
- 09/05/06: CIRB Acknowledgement of RDE Screens for Decentralized Genetic Stratification
- 09/01/06: Memo of RDE Screens for Decentralized Genetic Stratification
- 09/01/06: Memo of Revised Data Submission Schedule and Specimen Transmittal Form
- 09/05/06: CIRB Acknowledgement of Revised Data Submission Schedule and Specimen Transmittal Form

COG-AALL0331

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page
Documentation posted:



- 09/05/06: CIRB Acknowledgement of No Objection Letter for use of Erwinia asparaginase in COG protocols
- 09/01/06: Memo of No Objection Letter for use of Erwinia asparaginase in COG protocols

COG-AAML0531

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/11/06: CIRB Acknowledgement of Training Module for AAML0531
- 09/08/06: Memo of Training Module for AAML0531
- 09/05/06: CIRB Acknowledgement of A Phase III Randomized Trial of Gemtuzumab Ozogamicin (Mylotarg®)..... [Per Sept. 06]
- 09/05/06: CIRB Acknowledgement of A Phase III Randomized Trial of Gemtuzumab Ozogamicin (Mylotarg®)..... [Per Aug. 06]
- 09/01/06: Memo of A Phase III Randomized Trial of Gemtuzumab Ozogamicin (Mylotarg®).....
- 08/25/06: Memo of A Phase III Randomized Trial of Gemtuzumab Ozogamicin (Mylotarg®).....

COG-ACNS0221

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/05/06: CIRB Acknowledgement of Updated Eligibility CRF and Screen - Adding Optional Studies
- 08/18/06: Memo of Updated Eligibility CRF and Screen - Adding Optional Studies

COG-ACNS0224

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/05/06: CIRB Acknowledgement of A Phase I/II Study of Topotecan with G-CSF and Radiation Therapy In Children.....
- 08/18/06: Memo of A Phase I/II Study of Topotecan with G-CSF and Radiation Therapy In Children.....

COG-ACNS0423

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:



- 09/05/06: CIRB Acknowledgement of Updated Eligibility CRF and Screen - Amendment #1
- 09/01/06: Memo of Updated Eligibility CRF and Screen - Amendment #1

COG-ADVL0524

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/05/06: CIRB Acknowledgement of Changes to the Data Entry and Submission Schedule, On-Study Form and RDE screen
- 08/18/06: Memo of Changes to the Data Entry and Submission Schedule, On-Study Form and RDE screen

COG-AHOD03P1

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/11/06: CIRB Acknowledgement of Revised AHOD03P1 Data Submission Schedule
- 09/08/06: Memo of Revised AHOD03P1 Data Submission Schedule

COG-AHOD0431

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/11/06: CIRB Acknowledgement of Revised AHOD0431 Data Submission Schedule
- 09/11/06: CIRB Acknowledgement of A Phase III Study for the Treatment of Children and Adolescents.....
- 09/08/06: Memo of Revised AHOD0431 Data Submission Schedule
- 09/08/06: Memo of A Phase III Study for the Treatment of Children and Adolescents.....

COG-AOST0331

Amendment Review: CIRB Acknowledgement Memo listed under the Amendment Reviews tab on the CIRB web page

Documentation posted:

- 09/05/06: CIRB Acknowledgement of Revised AOST0331 Targeted Toxicity, Follow-up, and Death forms
- 08/18/06: Memo of Revised AOST0331 Targeted Toxicity, Follow-up, and Death forms



COG-ARST0431

Continuing Expedited Review September 2006

Documentation posted:

- CIRB Continuing Review Application Version 08/03/06
- 09/01/06, CIRB Approval to Continuing Review September 2006 (Protocol Version 08/03/06)
- Informed Consent for Protocol Version 08/03/06 [Per Sep. 06 CR]

ECOG-E3805

Continuing Expedited Review March 2006

Documentation posted:

- CIRB Continuing Review Application Version 02/23/06
- 03/21/06, CIRB Approval to Continuing Review March 2006 (Protocol Version 02/23/06): Local IRB
- 03/07/06, Continuing Review Notice for March 2006
- 03/21/06, CIRB Approval to Continuing Review March 2006 (Protocol Version 02/23/06): Study Chair
- Informed Consent for Protocol Version 02/23/06 [Per Mar. 06 CR]

SWOG-S0124

Amendment Expedited Review: Revision #7 (Protocol Version 07/06/06)

Documentation posted:

- CIRB Application Version 07/06/06
- Summary of CIRB Application Revisions Version 07/06/06
- 08/21/06: CIRB Approval to Revision #7 (Protocol Version 07/06/06)
- Protocol Version 07/06/06
- Informed Consent for Protocol Version 07/06/06

SWOG-S0226

Amendment Expedited Review: Revision #1 (Protocol Version 07/06/06)

Documentation posted:

- CIRB Application Version 07/06/06
- Summary of CIRB Application Revisions Version 07/06/06
- 08/21/06: CIRB Approval to Revision #1 (Protocol Version 07/06/06)
- Protocol Version 07/06/06
- Informed Consent for Protocol Version 07/06/06

Serious Adverse Events

Study: CALGB 80203

SAEs Posted: 06-02-08361 / DDL #219, 06-02-08265 (1) / DDL #213 (1)



Study: CALGB 80303
SAE Posted: AE 1322063

Study: CALGB 80405 – SWOG 80405
SAEs Posted: 06-02-08361 / DDL #219, 06-02-08265 (1) / DDL #213 (1), AE 1322063

Study: CALGB 90206
SAE Posted: AE 1322063

Study: CALGB 90401
SAE Posted: AE 1322063

Study: NCCTG N0147
SAEs Posted: 06-02-08361 / DDL #219, 06-02-08310 (1) / DDL #215 (1), 06-02-08310 (2) / DDL 215 (2), 06-02-08310 / DDL #215

Study: NSABP B-38
SAEs Posted: Safety Update #83, Safety Update #84. Safety Update #85, Safety Update #81 (FU 1), Safety Update #84 (FU 1)

Study: NSABP C-08
SAE Posted: AE 1322063

Study: RTOG 0522
SAEs Posted: 06-02-08501 / DDL #218, 06-02-08310 / DDL #215, 06-02-07899 (1) / DDL #210 (1), 06-02-08361 / DDL #219, 06-02-08310 (1) / DDL #215 (1), 06-02-08310 (2) / DDL 215 (2), 06-02-09124 / DDL #224, 06-02-09359 / DDL #225

Study: SWOG S0205
SAEs Posted: 06-02-07899 (1) / DDL #210 (1), 06-02-08361 / DDL #219, 06-02-08310 (1) / DDL #215 (1), 06-02-08310 (2) / DDL 215 (2), 06-02-09124 / DDL #224, 06-02-09359 / DDL #225

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@ctisinc.com.