



NCI Central IRB Protocol Activity Update August 16, 2006

The CIRB is distributing this protocol 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

NSABP-B-42

Initial Review 2006

Documentation posted:

- Protocol Version 04/07/06
- Informed Consent for Protocol Version 04/07/06: Main Study
- Informed Consent for Protocol Version 04/07/06: Registration Program
- CIRB Application Version 04/07/06
- Summary of CIRB Application Revisions Version 04/07/06
- 03/20/06: Primary Reviewer 1 Comments
- 03/20/06: Primary Reviewer 2 Comments
- 04/13/06: CIRB Approval (Protocol Version 04/07/06): Study Chair
- 04/13/06: CIRB Approval (Protocol Version 04/07/06): Local IRB
- 03/29/06: Approval Pending Modification (Protocol Version 02/15/06)
- 04/12/06: NSABP Response to Approval Pending Modification
- 04/07/06: Summary of Protocol and Consent Changes in NSABP-B-42
- 03/20/06: Initial Review Meeting Minutes

Pediatric CIRB Studies

COG-AAML0531

Initial Review 2006

Documentation posted:

- Protocol Version 05/09/06
- Protocol Version 05/09/06, Highlighted Changes
- Protocol Version 03/27/06
- Protocol Version 03/27/06, Highlighted Changes
- Protocol Version 01/10/06
- Informed Consent for Protocol Version 05/09/06
- CIRB Application Version 05/09/06
- CIRB Application Version 03/27/06
- CIRB Application Version 01/10/06
- 04/24/06: Primary Reviewer 1 Comments
- 04/24/06: Primary Reviewer 2 Comments
- 04/24/06: Primary Reviewer 3 Comments
- 02/23/06: Primary Reviewer 1 Comments
- 02/23/06: Primary Reviewer 2 Comments
- 02/23/06: Member 1 Comments
- 02/23/06: Member 2 Comments
- 02/23/06: Member 3 Comments
- 02/23/06: Pharmacy Reviewer Comments
- 05/10/06: CIRB Approval (Protocol Version 05/09/06): Study Chair



- 05/10/06: CIRB Approval (Protocol Version 05/09/06): Local IRB
- 05/09/06: COG Response
- 05/05/06: COG Response Approval Pending Modification (Protocol Version 03/27/06)
- 03/28/06: COG Response
- 03/02/06: Approval Pending Modification (Protocol Version 01/10/06)
- 04/24/06: Group Response Meeting Minutes
- 02/23/06: Initial Review Meeting Minutes

Amendment Review: Amendment #1 (Protocol Version 07/25/06)

Documentation posted:

- 07/25/06, Amendment #1
- CIRB Application Version 07/25/06
- 07/31/06: CIRB Approval to Amendment #1 (Protocol Version 07/25/06)
- Protocol Version 07/25/06
- Protocol Version 07/25/06, Highlighted Changes
- Informed Consent for Protocol Version 07/25/06

Other Activity Posted:

COG-AALL03B1

Acknowledgement: Documentation posted:

- 08/07/06: CIRB Acknowledgement of Memo re: Pilot Phase of Decentralized Cytogenetic Stratification
- 08/07/06: Memo re: Pilot Phase of Decentralized Cytogenetic Stratification

COG-AALL03N1

Amendment Review: Amendment #2 (Protocol Version 07/17/06)

Documentation posted:

- 05/15/06, Change Memo
- CIRB Application Version 05/15/06
- CIRB Application Version 07/17/06
- 07/14/06: CIRB Approval Pending Modification (Protocol Version 05/15/06)
- 07/17/06: COG Response
- 07/24/06: CIRB Approval to Amendment #2 (Protocol Version 07/17/06)
- 08/07/06: Study Activation
- 08/07/06: CIRB Acknowledgement of Activation
- Protocol Version 05/15/06
- Protocol Version 07/17/06
- Informed Consent for Protocol Version 07/17/06



COG-ANBL00P3

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

Documentation posted:

- 08/07/06: CIRB Acknowledgment of Posting
- 08/07/06: Revised Specimen Shipping Form

COG-AOST0331

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

Documentation posted:

- 08/07/06: CIRB Acknowledgement of Revised Forms
- 08/07/06: Revised Forms

NSABP-B-35

Amendment Review: Amendment #3 (Protocol Version 05/31/06)

Documentation posted:

- 06/19/06, Change Memo
- Summary of Protocol and Consent Changes Version 05/31/06
- CIRB Application Version 05/31/06
- Summary of CIRB Application Revisions (Protocol Version 05/31/06)
- 06/28/06: CIRB Approval to Amendment #3 (Protocol Version 05/31/06): Study Chair
- 06/28/06: CIRB Approval to Amendment #3 (Protocol Version 05/31/06): Local IRB
- Protocol Version 05/31/06
- Informed Consent for Protocol Version 05/31/06

NSABP-B-42

Amendment Review: Revision #4 (Protocol Version 07/12/06)

Documentation posted:

- 07/12/06: Summary of Protocol and Consent Changes in NSABP-B-42
- 07/14/06, Change Memo
- Summary of CIRB Application Revisions Version 07/12/06
- CIRB Application Version 07/12/06
- 08/01/06: CIRB Approval to Revision #4 (Protocol Version 07/12/06)
- 08/08/06: Notice of Protocol Approval
- Protocol Version 07/12/06
- Informed Consent for Protocol Version 07/12/06: Main Study
- Informed Consent for Protocol Version 07/12/06: Registration Program



Serious Adverse Events

Study: CALGB 80405, CALGB 80303, CALGB 90206, CALGB 90401, ECOG E1505, ECOG E2603, ECOG E2805, ECOG E3200, ECOG E2100, ECOG E4599, ECOG E5202, ECOG E5204, GOG 0218, NSABP B-40, NSABP C-08, SWOG S0502

SAE Posted: AE 1900831

Study: CALGB 80405, CALGB 80303, CALGB 90206, CALGB 90401, ECOG E1505, ECOG E2603, ECOG E2805, ECOG E3200, ECOG E2100, ECOG E4599, ECOG E5202, ECOG E5204, GOG 0218, NSABP B-40, NSABP C-08, SWOG S0502

SAE Posted: AE 1108237

Study: CALGB 90202

SAE Posted: 1034464

Study: CALGB 100104-ECOG 100104, ECOG E4A03, SWOG S0232

SAE Posted: 1544358

Study: CALGB 80203, CALGB 80303, CALGB 80405, CALGB 90401, CALGB 90206, ECOG 2100, ECOG 4599, ECOG 5202, ECOG 5204, GOG 0218, NSABP C-08

SAE Posted: 216549(1)

Study: ECOG E2603, ECOG E2805

SAE Posted: 1041096

Study: ECOG E4A03, SWOG S0232

SAE Posted: AE 1766366

Study: NCIC CTG MA.27

SAEs Posted: MAP3-1, 2006067898

Study: NSABP B-34

SAEs Posted: Safety Update #29, Safety Update #30

Study: NSABP B-36

SAE Posted: AE 1144732

Study: NSABP B-38

SAEs Posted: Safety Update #68 (Follow-up #1), Safety Update #69 (Follow-up #1), Safety Update #73 (Follow-up #1), Safety Update #73, Safety Update #74, Safety Update #75, Safety Update #76, Safety Update #76 (Follow-up #1), Safety Update #77, Safety Update #78, Safety Update #79, Safety Update #80, Safety Update #81, Safety Update #82



Study: RTOG 0522

SAEs Posted: 06-02-07899 / DDL #210, 06-02-08216 / DDL #211, 06-02-07936 / DDL #212

Study: SWOG S0124

SAEs Posted: AE 2006028443(1), AE 2006057230(1)

Study: SWOG S0200

SAEs Posted: AE 20060404543(0), AE 2002031781(3), AE 20060306520(5)

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.