



NCI Central IRB Study Activity Update

September 28, 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. ******



Activity Posted:

COG – AALL03B1

Amendment Review (AR): Amendment #4A

Documents Posted:

- CIRB Application Protocol Version Date 08/21/07
- 08/23/07: CIRB Approval of Amendment #4A (Protocol Version 08/21/07)
- 08/21/07: Change Memo
- Protocol Version Date 08/21/07
- Protocol Version Date 08/21/07 Highlighted
- Informed Consent Form for Protocol Version 08/21/07 - Additional Bone Marrow Collection
- Informed Consent Form for Protocol Version 08/21/07 - Study Entry & Sample Shipment

Continuing Review (CR): July 2007

Documents Posted:

- CIRB Review Application (Protocol Version Date 08/21/07)
- Protocol Version Date 08/21/07 Highlighted
- Protocol Version 08/01/06

COG – AALL0434

Continuing Review (CR): August 2007

Documents Posted:

- Continuing Review Application (Protocol Version Date 09/07/06)
- 09/24/07: CIRB Approval to Continuing Review August 2007 (Protocol Version Date 09/07/06)
- 09/20/07: Change Letter
- 09/17/07: CIRB Approval Pending Modifications to Continuing Review August 2007 (Protocol Version Date 09/07/06)
- Informed Consent Form Protocol Version 09/07/06: Part I - Induction Therapy
- Informed Consent Form Protocol Version 09/07/06: Part II - Low Risk
- Informed Consent Form Protocol Version 09/07/06: Part II - Intermediate Risk
- Informed Consent Form Protocol Version 09/07/06: Part II - High Risk
- Informed Consent Form Protocol Version 09/07/06: Part II - Induction Failure
- Informed Consent Form Protocol Version 09/07/06: Optional Pharmacokinetic



COG – ACCL04C2

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/11/07)
- CIRB Continuing Review Application (Protocol Version Date 08/08/05)
- 09/17/07: CIRB Approval to Continuing Review September 2007 (Protocol Version Date 09/11/07)
- 09/11/07: Change Memo
- 09/10/07: CIRB Approval Pending Modification of Continuing Review August 2007
- Protocol Version Date 09/11/07
- Protocol Version Date 09/11/07 Highlighted
- Protocol Version 08/08/05
- Informed Consent Form (Protocol Version Date 09/11/07)
- Study Committee Progress Report 03/30/07

COG – ACNS0334

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/15/07)
- 09/18/07: CIRB Approval to Continuing Review September 2007 (Protocol Version Date 06/15/07)
- Protocol Version Date 06/15/07
- Informed Consent Form for Protocol Version Date 06/15/07

COG – AHOD0521

Temporary Suspension of Accrual

Documents Posted:

- 09/28/07: CIRB Acknowledgement of Temporary Suspension of Accrual
- 09/28/07: Memo re Temporary Suspension of Accrual for Study AHOD0521

COG – ANBL00B1

Amendment Review (AR): Amendment #7

Documents Posted:

- Amendment #7 Protocol Version Date 08/06/07
- CIRB Application Protocol Version Date 08/06/07
- 08/23/07: CIRB Approval of Amendment #7 (Protocol Version Date 08/06/07)
- 08/06/07: Change Memo



- Protocol Version Date 08/06/07
- Protocol Version Date 08/06/07 Highlighted

Continuing Review (CR): July 2007

Documents Posted:

- CIRB Review Application Protocol Version Date 08/06/07
- Protocol Version Date 08/06/07 Highlighted
- Protocol Version 08/18/06

COG – ANBL0322

Closed to Accrual

Documents Posted:

- 09/28/07: Acknowledgement of Closure of Study ANBL0322
- 09/28/07: Memo re Closure of Study ANBL0322

COG – ARAR0331

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/25/05)
- 09/18/07: CIRB Approval to Continuing Review September 2007 (Protocol Version Date 05/25/07)
- 09/14/07: Group Response Change Letter
- 09/13/07: Group Response Letter
- 09/10/07: CIRB Approval Pending Modification of Continuing Review
- Informed Consent Form (Protocol Version Date 05/25/05)
- 04/17/07: DSMC Report
- Study Progress Report 03/30/07

COG – AREN0321

Continuing Review (CR): August 2007

Documents Posted:

- Continuing Review Application (Protocol Version Date 11/20/06)
- 09/24/07: CIRB Approval to Continuing Review August 2007 (Protocol Version Date 11/20/06)
- 09/19/07: Response Letter
- 09/17/07: CIRB Approval Pending Modifications to Continuing Review August 2007 (Protocol Version Date 11/20/06)
- Informed Consent Form Protocol Version Date 11/20/06: Regimen DD-4A
- Informed Consent Form Protocol Version Date 11/20/06: Observation
- Informed Consent Form Protocol Version Date 11/20/06: Regimen I
- Informed Consent Form Protocol Version Date 11/20/06: Regimen UH1



- Informed Consent Form Protocol Version Date 11/20/06: Window Therapy
- 04/20/07: DSMC Report
- Study Progress Report 03/30/07

COG – ARET0331

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 09/14/07)
- CIRB Continuing Review Application (Protocol Version Date 04/17/06)
- 09/17/07: CIRB Approval to Continuing Review September 2007 (Protocol Version Date 09/14/07)
- 09/14/07: Group Response to Approval Pending Modifications
- 09/14/07: Group Response Letter
- Protocol Version Date 09/14/07
- Protocol Version Date 09/14/07 highlighted
- Protocol Version 04/17/06
- Informed Consent Form Protocol Version Date 09/14/07
- 04/17/07: DSMC Report
- Study Progress Report 03/30/07

COG – ARST0531

Continuing Review (CR): August 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/16/06)
- 09/14/07: CIRB Approval to Continuing Review August 2007 (Protocol Version Date 10/16/06)
- 09/11/07: Response Letter
- 09/10/07: CIRB Approval Pending Modifications to Continuing Review August 2007 (Protocol Version Date 10/16/06)
- Protocol Version 10/16/06
- Informed Consent Form (Protocol Version Date 10/16/06) [per Aug 07 CR]
- 04/17/07: DSMC Report

ECOG – E1505

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/26/07)
- 09/13/07 Full Board Approval Letter
- Protocol Version Date 06/26/07
- Informed Consent Form for Protocol Version Date 06/26/07 [per CR Sep 07]
- Study Summary



ECOG – E2100

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/30/07)
- 09/18/07: CIRB Continuing Review Approval September 2007 (Protocol Version 05/30/07)
- Protocol Version Date 05/30/07
- DMC Report March, April 2005

ECOG – E3200

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 03/07/07)
- 09/18/07: Approval Letter
- Protocol Version 03/07/07
- 11/02/04: DMC Report
- Report of Studies Dated November 2004

ECOG – E4402

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/28/06)
- 09/18/07: CIRB Continuing Review Approval September 2007 (Protocol Version 07/28/06)
- Protocol Version 07/28/06
- Informed Consent for Protocol Version 07/28/06 [per Sep 07 CR]
- Report of Studies Dated June 2007
- 05/02/07: DMC Report

ECOG – E4A03

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 05/30/07)
- 09/20/07 CIRB Continuing Review Approval September 2007 (Protocol Version 05/30/07)
- Protocol Version 05/30/07
- ASCO 2007 Abstract 2007 ASCO Annual Meeting
- Changes to the Informed Consent
- Report of Studies Dated June 2007
- 05/02/07 DMC Minutes



ECOG – PACCT-1

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 07/16/07)
- 09/24/07 CIRB Continuing Review Approval September 2007 (Protocol Version 07/16/07)
- Protocol Version 07/16/07
- Informed Consent for Protocol Version 07/16/07 [per September 2007 CR]
- 05/02/07 DMC Report
- Report of Studies Dated June 2007

NCIC CTG BR.19

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 01/03/05)
- 09/18/07: CIRB Continuing Review Approval September 2007 (Protocol Version 01/03/05)
- Protocol Version 01/03/05
- Report of Studies Dated 02/20/07

NSABP-B-36

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/20/07)
- 09/27/07: Continuing Review Approval September 2007 (Protocol Version 04/20/07)
- 08/03/07: Cover Letter
- Protocol Version 04/20/07
- Informed Consent for Protocol Version 04/20/07 [per Sep 07 CR]
- 04/13/07 DMC Report
- 10/20/06 DMC Report
- Report of Studies Dated September 2007

NSABP-C-08

Continuing Review (CR): September 2007

Documents Posted:

- CIRB Continuing Review Application (Protocol Version 04/21/06)
- 09/27/07: CIRB Continuing Review Approval September 2007 [per Sep 07 CR]
- Protocol Version 04/21/07
- 04/13/07: DMC Report



- 10/20/06: DMC Report
- Report of Studies Dated September 2007
- 08/07/07: Cover Letter

Corrections to Previous Study Activity Updates

COG – ADVL0524

Amendment Review: Amendment #1

Correction: The ADVL0524 Amendment #1 was posted in April 2007 but it was not included in the April 15, 2007 Study Activity Update. The Study Activity Update dated 09/14/07 incorrectly listed this as Amendment #3 in the Corrections to Previous Study Activity Updates section.

If you have any questions about your local review process, please contact your Local IRB office.

General CIRB Documentation

Serious Adverse Events

Study: ECOG E1302

SAE Posted: ZD1839 (IND 61187) Investigator Notification

Study: NSABP B-34

SAE Posted: GB-2007-010897 (1) / Safety Update # 45 (1)

Study: RTOG 0320

SAE's Posted: 2006SP008904, 2007SP000438, 2007SP000438 (1), 2007SP006588 (1), 2007SP006588 (2), 2007SP012156, 2007SP012156 (1), 2007SP012478 (1)

Study: RTOG 0525

SAE's Posted: 2006SP008904, 2007SP000438, 2007SP000438 (1), 2007SP006588 (1), 2007SP006588 (2), 2007SP012156, 2007SP012156 (1), 2007SP012478 (1)

Study: SWOG S0307

SAE Posted: GB-2007-010897 (1) / Safety Update # 45 (1)



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