



NCI Central IRB Study Activity Update

April 15, 2009

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:

CALGB-10603

Amendment Review (AR): Update #2 (Protocol Version date 02/06/09)

Documents Posted:

- CALGB Change Memo (Protocol Version Date 02/06/09)
- CIRB Application (Protocol Version Date 02/06/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/06/09)
- 03/09/09: CIRB Update 2 Approval Letter (Protocol Version Date 02/06/09)
- Protocol Version Date 02/06/09
- Informed Consent Document for Protocol Version Date 02/06/09 [Up 2]
- 03/06/09: Primary Reviewer 1 Comments

CALGB-40503

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/14/08)
- 04/08/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/14/08)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 02/14/08
- Informed Consent Document for Protocol Version Date 02/14/08 [CR09]
- 04/03/09: Primary Reviewer Comments

CALGB-50303

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/02/08)
- 04/08/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/02/08)
- 02/05/09: Continuing Review Reminder Notice
- Protocol Version Date 06/02/08
- Informed Consent Document for Protocol Version Date 06/02/08 [CR09]
- 11/14/08: DSMB Report
- November 2008 - Study Summary
- 04/03/09: Primary Reviewer Comments



CALGB-90203

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 07/17/08)
- 04/07/09: CIRB Continuing Review Approval with Query (Protocol Version Date 07/17/08)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 07/17/08
- Informed Consent Document for Protocol Version Date 07/17/08 [CR09]
- 03/16/09: Primary Reviewer 1 Comments
- 11/14/08: DSMB Report
- November 2008 - Study Summary

COG-AALL0331

****Closure of HRQOL Ancillary Study by COG – Effective March 20, 2009****

Amendment Review (AR): **Acknowledgement of COG AALL0331 Closure of HRQOL Ancillary Study**

Documents Posted:

- 04/02/09: CIRB Acknowledgement - Closure of HRQOL Ancillary Study
- 03/20/09: COG Memo - Closure of HRQOL Ancillary Study

COG-AALL0631

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/02/07) – Revised
- CIRB Continuing Review Application (Protocol Version Date 11/02/07)
- 03/30/09 CIRB Continuing Review Approval Letter (Protocol Version Date 11/02/07)
- 03/24/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/02/07)
- 02/27/09: CIRB Approval Pending Modification Letter (Protocol Version Date 11/02/07)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/02/07
- Informed Consent Document for Protocol Version Date 11/02/07 - Part 1 Phase 1
- Informed Consent Document for Protocol Version Date 11/02/07 - Part 1 Non-Phase 1



- Informed Consent Document for Protocol Version Date 11/02/07 - Part 2
- 02/12/09: Primary Reviewer 1 Comments
- 02/12/09: Minutes - Continuing Review
- 10/02/08: DSMC Report
- 08/25/08: Study Progress Report

COG-AAML0523

****Temporarily Closed to Accrual by COG - Effective April 3, 2009****

Amendment Review (AR): **Acknowledgement of COG AAML0523 Temporary Closure to Accrual (04/03/09)**

Documents Posted:

- 04/03/09: CIRB Acknowledgement of Receipt-Temporary Closure to Accrual
- 04/03/09: COG Temporary Closure to Accrual-Effective April 3, 2009

COG-ACCL04C2

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/27/08)
- 03/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/27/08)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 02/27/08
- Informed Consent Document for Protocol Version Date 02/27/08
- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review
- Study Progress Report - Spring 2009

COG-ACCL0631

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/07/08)
- 03/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/07/08)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 02/07/08
- Informed Consent Document for Protocol Version Date 02/07/08
- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review



- Study Progress Report - Spring 2009
- 08/25/08: Study Progress Report

Amendment Review (AR): Amendment #1 (Protocol Version Date 01/30/09)

Documents Posted:

- CIRB Application (Protocol Version Date 01/30/09)
- 04/01/09: CIRB Approval of COG ACCL0631 Amendment #1 (Protocol Version Date 01/30/09)
- 01/30/09: COG Change Memo (Protocol Version Date 01/30/09)
- Protocol Version Date 01/30/09
- Protocol Version Date 01/30/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 01/30/09

COG-ACCRN07

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/06/08)
- 03/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/06/08)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 08/06/08
- Informed Consent Document for Protocol Version Date 08/06/08 - Patient Consent
- Informed Consent Document for Protocol Version Date 08/06/08 - Parental Consent
- Assent Form Document for Protocol Version Date 08/06/08
- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review
- Permission Forms for ACCRN07 (Protocol Version Date 08/06/08)
- Information Sheet for ACCRN07 (Protocol Version Date 08/06/08)
- Study Progress Report - Fall 2008

COG-ACNS0221

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/15/05)
- 03/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/15/05)



- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 11/15/05
- Informed Consent Document for Protocol Version Date 11/15/05
- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review
- Study Progress Report - Spring 2009

COG-AEPI05N1

Amendment Review (AR): **[Acknowledgement of Correction to Amendment #3](#)**

Documents Posted:

- 03/31/09: CIRB Acknowledgement of the Correction to Amendment #3 Cover Page
- 03/02/09: COG AEPI05N1 Reactivation Memo

COG-AHOD0431

****Closed to Accrual by COG - Effective April 3, 2009****

Amendment Review (AR): **[Acknowledgement of AHOD0431 Study Closure \(04/03/09\)](#)**

Documents Posted:

- 04/03/09: CIRB Acknowledgement of Receipt-Closure to Accrual
- 04/03/09: COG Closure to Patient Accrual-effective April 3, 2009
- Informed Consent Document for Protocol Version 05/11/07: Initial Treatment
- Informed Consent Document for Protocol Version 05/11/07: Relapse Treatment

COG-AOST06B1

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/26/07)
- 04/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/26/07)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 11/26/07
- Informed Consent Document for Protocol Version Date 11/26/07 - Newly-Diagnosed Osteosarcoma
- Informed Consent Document for Protocol Version Date 11/26/07 - Recurrent Osteosarcoma
- 08/25/08: Study Committee Progress Report



COG-ARAR0331

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/25/05)
- 03/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/25/05)
- 02/05/09: Continuing Review Reminder Notice
- Protocol Version Date 05/25/05
- Informed Consent Document for Protocol Version Date 05/25/05
- 03/12/09: Primary Reviewer 1 Comments
- 11/05/08: DSMC Report
- 08/25/08: Study Progress Report

COG-ARST0431

Continuing Review (CR): Continuing Review February 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/26/07)
- 03/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/07)
- 03/25/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 06/26/07)
- 03/06/09: Vincristine Administration Guidelines
- 03/03/09: CIRB Approval Pending Modification Letter (Protocol Version Date 06/26/07)
- 01/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/26/07
- Informed Consent Document for Protocol Version Date 06/26/07
- 02/12/09: Primary Reviewer 1 Comments
- 02/12/09: Minutes - Continuing Review

ECOG-E1305

Amendment Review (AR): Update #2 (Protocol Version date 03/18/09)

Documents Posted:

- 03/18/09: ECOG Change Memo (Protocol Version Date 03/18/09)
- CIRB Application (Protocol Version Date 03/18/09)
- Summary CIRB Application Revisions (Protocol Version Date 03/18/09)
- 04/06/09: CIRB Update 2 Approval Letter (Protocol Version Date 03/18/09)
- Protocol Version Date 03/18/09



- Informed Consent Document for Protocol Version Date 03/18/09 [up2]

ECOG-E1505

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/18/09)
- 04/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/18/09)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 01/07/09
- Informed Consent Document for Protocol Version Date 01/07/09 [CR09]
- Study Summary Dated November 2008
- 10/29/08: DMC Recommendations
- 04/03/09: Primary Reviewer 1 Comments

ECOG-PACCT-1

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/18/09)
- 04/08/09: CIRB Continuing Review Approval (Protocol Version Date 03/18/09)
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 03/18/09
- Informed Consent Document for Protocol Version Date 03/18/09 [CR09]
- November 2008 - Study Summary
- October-November 2008 - DMC Recommendations
- 04/03/09: Primary Reviewer 1 Comments

GOG-0212

Amendment Review (AR): Revision #6 (Protocol Version date 03/18/09)

Documents Posted:

- 03/18/09: GOG Change Memo (Protocol Version Date 03/18/09)
- CIRB Application (Protocol Version Date 03/18/09)
- Summary of CIRB Application Revisions (Protocol Version Date 03/18/09)
- 03/19/09: CIRB Revision 6 approval Letter (Protocol Version Date 03/18/09)
- 03/13/09: CIRB Approval Pending Modifications Letter (Protocol Version Date 02/27/09)
- Protocol Version Date 03/18/09
- Informed Consent Document for Protocol Version Date 03/18/09 [Rev6]



GOG-0219

Amendment Review (AR): Revision #7 (Protocol Version date 02/24/09)

Documents Posted:

- 02/24/09: GOG Change Memo (Protocol Version Date 02/24/09)
- CIRB Application (Protocol Version Date 02/24/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/24/09)
- 03/17/09: CIRB Revision 7 Approval Letter (Protocol Version Date 02/24/09)
- Protocol Version Date 02/24/09
- Protocol Version Date 02/24/09 (Highlighted)
- APPENDIX I: EXTRAPERITONEAL LYMPH NODE SAMPLING
- APPENDIX II: PELVIC AND PARA-AORTIC NODE SAMPLING
- APPENDIX III: CLINICAL STAGING - CARCINOMA OF THE CERVIX UTERI
- APPENDIX IV: HDR BRACHYTHERAPY
- APPENDIX IV: HDR BRACHYTHERAPY (Highlighted)
- APPENDIX V: Blank Diagram Anterior
- APPENDIX VI: BLANK DIAGRAM LATERAL
- APPENDIX VII: Description of ICRU
- APPENDIX VIII: Radiotherapy Information for Canadian Centers
- APPENDIX IX: Information for ANZGOG Institutions (02/06/2006)
- APPENDIX X: Specimen Procedures
- APPENDIX XI: Laboratory Procedures
- APPENDIX XII: NCI Standard Protocol Language
- APPENDIX XIII: LOGISTICAL GUIDELINES FOR CTSU
- Informed Consent Document for Protocol Version Date 02/24/09 [Rev7]

NSABP-C-08

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/25/07)
- 04/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/25/07)
- 03/13/09: NSABP Cover Memo
- 02/06/09: Continuing Review Reminder Notice
- Protocol Version Date 10/25/07
- Informed Consent Document for Protocol Version Date 10/25/07 [CR09]
- Informed Consent Document for Protocol Version Date 10/25/07: Add1
- Informed Consent Document for Protocol Version Date 10/25/07: Add2
- 10/17/08: DMC Minutes



- 04/25/08: DMC Minutes
- Journal of Clinical Oncology - Abstract 4006
- Study Summary

NSABP-R-04

Amendment Review (AR): CIRB Acknowledgement of Updated Oxaliplatin Investigator Brochure

Documents Posted:

- 03/27/09: Acknowledgement of Receipt for Updated Oxaliplatin IB dated 05/17/07

RTOG-0436

Amendment Review (AR): Amendment #1 (Protocol Version Date 02/13/09)

Documents Posted:

- CIRB Application (Protocol Version Date 02/13/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/13/09)
- 03/17/09: CIRB Amendment 1 Approval Letter (Protocol Version Date 02/13/09)
- 02/13/09: RTOG Cover Memo
- Protocol Version Date 02/13/09
- Protocol Version Date 02/13/09 (Highlighted)
- Informed Consent Document for Protocol Version Date 02/13/09 [Am1]

RTOG-0436

Amendment Review (AR): 03/31/09 Update (Protocol Version Date 02/13/09)

Documents Posted:

- 04/01/09: Change Memo (Protocol Version Date 02/13/09)
- 04/01/09: CIRB 03/31/09 Update Approval Letter (Protocol Version Date 2/13/09)
- Protocol Version Date 02/13/09
- Protocol Version Date 02/13/09 (Highlighted)
- Informed Consent Document for Protocol Version Date 02/13/09 [033109 Up]

RTOG-0534

Amendment Review (AR): Amendment #1 (Protocol Version Date 01/08/09)

Documents Posted:



- 01/08/09: Change Memo (Protocol Version Date 01/08/09)
- CIRB Application (Protocol Version Date 01/08/09)
- Summary of CIRB Application Revisions (Protocol Version Date 01/08/09)
- 03/31/09: Acknowledgement of Posting of Amendment #1 (Protocol Version Date 01/08/09)
- 03/06/09: CIRB Amendment 1 Approval Letter with Query (Protocol Version Date 01/08/09)
- Protocol Version Date 01/08/09
- Protocol Version Date 01/08/09 (Highlighted)
- Informed Consent Document for Protocol Version Date 01/08/09 [Am1]
- 02/23/09: Primary Reviewer 1 Comments

RTOG-0534

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/08/09)
- 04/07/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/08/09)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 01/08/09
- Informed Consent Document for Protocol Version Date 01/08/09 [CR09]
- 03/16/09: Primary Reviewer 1 Comments
- 01/09/09: DMC Minutes
- January 2009 - Study Summary

RTOG-0617

Amendment Review (AR): Amendment #3 (Protocol Version Date 03/09/09)

Documents Posted:

- 03/20/09: Change Memo (Protocol Version Date 03/29/09)
- CIRB Application (Protocol Version Date 03/09/09)
- Summary of CIRB Application Revisions (Protocol Version Date 03/09/09)
- 03/27/09: CIRB Amendment 3 Approval Letter (Protocol Version Date 03/09/09)
- 03/09/09: RTOG Cover Memo
- Protocol Version Date 03/09/09
- Informed Consent Document for Protocol Version Date 03/09/09 [Am3]

SWOG-S0518

Amendment Review (AR): Revision #2 (Protocol Version Date 02/20/09)

Documents Posted:



- 02/20/09: SWOG Change Memo (Protocol Version Date 02/20/09)
- CIRB Application (Protocol Version Date 02/20/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/20/09)
- 03/19/09: CIRB Approval Letter Revision 2 (Protocol Version Date 02/20/09)
- Protocol Version Date 02/20/09
- Informed Consent Document for Protocol Version Date 02/20/09 [Rev2]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 02/20/09

SWOG-S0521

Continuing Review (CR): Continuing Review April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/05/08)
- 04/08/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/05/08)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 10/05/08
- Informed Consent Document for Protocol Version Date 10/05/08 [CR09]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 10/05/08
- 10/31/08: DSMC Minutes
- October-November 2008 - Study Summary
- Primary Reviewer 1 Comments

Serious Adverse Events

Study: CALGB 40502

SAE Posted: 1205386 FU1, 1433885, 1477246 FU1, 1636469 FU1, 1809808 FU1, 1843518 FU2, 1881593

Study: CALGB 40503

SAE Posted: 1205386 FU1, 1433885, 1477246 FU1, 1636469 FU1, 1809808 FU1, 1843518 FU2, 1881593

Study: CALGB 80203

SAE Posted: 08-02-15603 FU2, 08-02-15765 FU3, 09-02-15897 FU1, 09-02-15962 FU1, 09-02-15966 FU1

Study: CALGB 80303



SAE Posted: 1205368 FU1, 1324148, 1433885, 1477246 FU1, 1636469 FU1, 1729567 FU1, 1803957 FU1, 1809808 FU1, 1843518 FU2, 1881593, 1996104, 273064

Study: ECOG E1105

SAE Posted: 1118620, 1118620 FU1, 1205368 FU1, 1324148, 1433885, 1475911, 1580693, 1636469 FU1, 1729567 FU1, 1803957 FU1

Study: GOG 0213

SAE Posted: 1118620 FU1, 1205368, 1205368 FU1, 1324148, 1354425 FU1, 1433885, 1477246, 1477246 FU1, 1580693, 1729567, 1729567 FU1, 1803957, 1803957 FU1, 1809808 FU1, 1843518 FU2, 1859262 FU1, 1881593, 1951869, 267119 FU2, 270229, 556768 FU1
