



NCI Central IRB Website Postings Summary

July 15, 2009

The NCI CIRB Operations Office is distributing this Website Postings Summary to all CIRB sites to provide a summary of the review documents posted to the CIRB website (<http://www.ncicirb.org/>) since the last update. Please note: for a complete listing of all documents pertaining to a specific review, visit the study-specific webpage.

Although these summary posting updates are provided on the 1st and 15th of every month, the CIRB Operations Office posts review documents and updates to the CIRB website on a daily basis.

All review documents are posted on the study-specific webpages. All notices are posted under the "What's New" section of the CIRB homepage. If you are unsure of your username and password or have difficulty accessing the website, please email ncicirbcontact@emmes.com or call the CIRB HelpDesk toll-free at 888-657-3711.

CIRB Notices

1. Please note the new name, "Website Postings Summary", replaces the current "Study Activity Update" to clarify the intent of this communication.
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Study-Specific Review Documents Recently Posted

Posted Documents Related to Initial Reviews:

The review documents listed below pertain to initial CIRB reviews. These new studies are now available for facilitated review.

Adult Studies

None

Pediatric Studies

COG-AREN0534

Initial Review 2007 Approval

Documents Posted:

- Protocol
 - Protocol Version Date 06/12/09
 - Protocol Version Date 06/12/09 - Highlighted Changes
 - Protocol Version Date 03/27/09
 - Protocol Version Date 03/27/09 - Highlighted Changes
 - Protocol Version Date 01/15/08
 - Protocol Version Date 01/15/08 - Highlighted Changes
 - Protocol Version Date 09/26/07
 - Protocol Version Date 09/26/07 - Highlighted Changes
 - Protocol Version Date 05/07/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 06/12/09 - Bilateral Wilms Tumor
 - Informed Consent Document for Protocol Version Date 06/12/09 - Bilaterally-Predisposed Unilateral Wilms Tumor
 - Informed Consent Document for Protocol Version Date 06/12/09 - Diffuse Hyperplastic Perilobar Nephrogenic Rests
- CIRB Application
 - CIRB Application (Protocol Version Date 06/12/09)
 - CIRB Application (Protocol Version Date 03/27/09)
 - CIRB Application (Protocol Version Date 01/15/08)
 - CIRB Application (Protocol Version Date 09/26/07)
 - CIRB Application (Protocol Version Date 05/07/07)



- Primary Reviews
 - 05/14/09: Primary Reviewer 1 Comments
 - 05/14/09: Primary Reviewer 2 Comments
 - 05/14/09: Pharmacist Reviewer Comments
 - 02/14/08: Primary Reviewer 1 Comments
 - 11/08/07: Primary Reviewer 1 Comments
 - 06/14/07: Primary Reviewer 1 Comments
 - 06/14/07: Primary Reviewer 2 Comments

- Correspondence
 - 07/13/09: COG Activation AREN0534 Memo
 - 06/24/09: CIRB Final Approval Letter of AREN0534 (Protocol Version Date 06/12/09)
 - 06/12/09: COG Response to Approval Pending Modification Letter of the Group Response to the Initial Review of AREN0534 (Protocol Version Date 03/27/09)
 - 05/29/09: CIRB Approval Pending Modification Letter of the Group Response to the Initial Review of AREN0534 (Protocol Version Date 03/27/09)
 - 03/27/09: COG Response Letter to Approval Pending Modification Letter of the Group Response to the Initial Review of AREN0534 (Protocol Version Date 01/15/08)
 - 02/29/08: CIRB Approval Pending Modification Letter of the Group Response to the Initial Review of AREN0534 (Protocol Version Date 01/15/08)
 - 01/15/08: COG Response to Table Letter of Group Response to Initial Review of AREN0534 (Protocol Version Date 09/26/07)
 - 12/11/07: CIRB Table Letter of Group Response to Initial Review of AREN0534 (Protocol Version Date 09/26/07)
 - 09/26/07: COG Response to Tabled Letter of Initial Review of AREN0534 (Protocol Version Date 05/07/07)
 - 07/27/07: CIRB Table Letter of Initial Review of AREN0534 (Protocol Version Date 05/07/07)

- Minutes
 - 05/14/09: Minutes - Group Response to Initial Review
 - 02/14/08: Minutes - Group Response to Tabled Initial Review
 - 11/08/07: Minutes - Group Response to Initial Review
 - 06/14/07: Minutes - Initial Review

Posted Documents Related to Amendment Reviews:

Adult Studies

ECOG-E1A05



Amendment Review (AR): Update #1 (Protocol Version Date 07/08/09)

Documents Posted:

- Amendments
 - 07/08/09: Change Memo (Protocol Version Date 07/08/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 07/08/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/08/09)
- Correspondence
 - 07/14/09: CIRB Update 1 Approval Letter (Protocol Version Date 07/08/09)
- Protocol
 - Protocol Version Date 07/08/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/08/09 [Up1]

ECOG-E2603

Amendment Review (AR): CIRB Acknowledgement-Dear Participant Letter, Dear Doctor Letter and DMC Outcome Memo

Documents Posted:

- Correspondence
 - 06/30/09: CIRB Acknowledgement of Dear Doctor, Dear Participant, and DMC Outcome Memo
 - 04/27/09: DMC Recommendation Memo
- Support Documents
 - Letter to Doctors
 - Letter to Participants

ECOG-E5103

Amendment Review (AR): Update #4 (Protocol Version Date 07/10/09)

Documents Posted:

- Amendments
 - 07/10/09: Change Memo (Protocol Version Date 07/10/09)



- Correspondence
 - 07/13/09: CIRB Update 4 Approval Letter (Protocol Version Date 07/10/09)
- Protocol
 - Protocol Version Date 07/10/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/10/09 [up4]

ECOG-E5204

Amendment Review (AR): CIRB Acknowledgement-Dear Participant Letter, Dear Doctor Letter (Memo dates 04/17/09)

Documents Posted:

- Correspondence
 - 07/13/09: CIRB Acknowledgement of Receipt for Participant and Doctor Letters
- Support Documents
 - Dear Doctor Letter
 - Dear Participant Letter

RTOG-0412-SWOG-S0332

****Completed (No Further Activity Conducted) – Effective January 2009****

Amendment Review (AR): CIRB Closure Due to Study Completion

Documents Posted:

- Correspondence
 - 07/06/09: CIRB Closure Due to Study Completion
 - January 2009: RTOG/SWOG Final Report

SWOG-S0226

****Closed to Accrual – Effective July 1, 2009****

Amendment Review (AR): CIRB Acknowledgement - Permanent Closure to Accrual Effective July 1, 2009

Documents Posted:

- Correspondence
 - 06/16/09: CIRB Acknowledgement of Permanent Closure
 - 06/01/09: SWOG Permanent Closure Memo



SWOG-S0421

Amendment Review (AR): Revision #3 (Protocol Version Date 03/20/09)

Documents Posted:

- Amendments
 - 03/20/09: Change Memo (Protocol Version Date 03/20/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 03/20/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 03/20/09)
- Correspondence
 - 04/09/09: CIRB Approval Letter Revision 3 (Protocol Version Date 03/20/09)
- Protocol
 - Protocol Version Date 03/20/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 03/20/09 [Rev3]
 - Informed Consent Document (Instructions for Local institutions) for Protocol Version Date 03/20/09

Amendment Review (AR): Revision #4 (Protocol Version Date 06/08/09)

Documents Posted:

- Amendments
 - 06/08/09: Change Memo (Protocol Version Date 06/08/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 06/08/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/08/09)
- Correspondence
 - 6/11/09: CIRB Revision 4 Approval Letter Revision 4 (Protocol Version Date 06/08/09) [Rev4]
- Protocol
 - Protocol Version Date 06/08/09
- Informed Consent



- CIRB's Informed Consent Document For Protocol Version Date (Protocol Version Date 06/08/09) [Rev4]
- CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 06/08/09

SWOG-S0500

Amendment Review (AR): Revision #3 (Protocol Version Date 06/01/09)

Documents Posted:

- Amendments
 - 06/01/09: Change Memo (Protocol Version Date 06/01/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 06/01/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/01/09)
- Correspondence
 - 06/16/09: CIRB Revision 3 Approval Letter (Protocol Version Date 06/01/09)
- Protocol
 - Protocol Version Date 06/01/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/01/09 [Rev 3]

SWOG-S0777

Amendment Review (AR): Revision #3 (Protocol Version Date 05/08/09)

Documents Posted:

- Amendments
 - 05/08/09 Change Memo (Protocol Version Date 05/08/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 05/08/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 05/08/09)
- Correspondence
 - 06/11/09: CIRB Revision 3 Approval Letter (Protocol Version Date 05/08/09)



- Protocol
 - Protocol Version Date 05/08/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/08/09 [Rev3]
 - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 05/08/09 [Rev3]

Pediatric Studies

COG-ANBL0532

Amendment Review (AR): **ANBL0532 Memo re Revised Requirements for Obtaining GFR/Creatinine Clearance during Induction**

Documents Posted:

- Correspondence
 - 07/01/09: CIRB Acknowledgement of COG ANBL0532 Memo Obtaining GFR/Creatinine Clearance during Induction
 - 06/26/09: COG Memo - Revised requirements for obtaining GFR/Creatinine Clearance during induction

COG-ARST0332

Amendment Review (AR): **ARST0332 Memo re Tracked Changes Risk Table for Sargramostim for Amendment #1B ICD**

Documents Posted:

- Correspondence
 - 07/01/09: CIRB Acknowledgement of COG ARST0332 Memo - Tracked Changes for Sargramostim Risk Table
 - 06/19/09: COG Memo - Sargramostim (GM-CSF) Risk Tables

Posted Documents Related to Continuing Reviews:

Adult Studies

CALGB-140503

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 02/15/08)
- Correspondence
 - 07/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/15/08)
 - 05/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 02/15/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 02/15/08 [CR09]
- Primary Reviews
 - 07/02/09: Primary Reviewer 1 Comments
- Support Documents
 - 11/14/08: DSMB Report
 - November 2008 Study Summary

ECOG-E2902

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/07/09)
- Correspondence
 - 07/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/07/09)
 - 05/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 04/07/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 04/07/09 [CR09]
- Primary Reviews
 - 07/02/09: Primary Reviewer 1 Comments



- Support Documents
 - June 2009 - Study Summary
 - April 2008 - DMC Recommendations

ECOG-E4201

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 03/07/07)
- Correspondence
 - 07/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/07/07)
 - 04/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 03/07/07
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/07/07 [CR09]
- Support Documents
 - 09/24/07: DMC Recommendations
 - November 2007 - Study Summary

GOG-0218

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 05/18/09)
- Correspondence
 - 07/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/18/09)
 - 05/04/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 05/18/09



- Appendix I-FIGO Stage Grouping for Primary Carcinoma of the Ovary
- Appendix II-Glossary of Terms
- Appendix III-NCI Standard Protocol Language
- Appendix IV-Electronic Patient Registration and Randomization
- Appendix V-Anaphylaxis Precautions
- Appendix VI-Specimen Procedures
- Appendix VII-Laboratory Procedures

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/18/09 [CR09]

- Primary Reviews
 - 07/02/09: Primary Reviewer 1 Comments

- Support Documents
 - 01/24/09: DSMB
 - January 2009 - Study summary

NCIC CTG-PR.11

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/08/09)

- Correspondence
 - 07/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/08/09)
 - 05/07/09: Continuing Review Reminder Notice

- Protocol
 - Protocol Version Date 04/08/09

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 04/08/09 [CR09]

- Primary Reviews
 - 06/18/08: Primary Reviewer 1 Comments

- Support Documents
 - Spring 2009 - Study Summary



- 08/20/08: JNCI Article

RTOG-0232

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/11/08)
- Correspondence
 - 07/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/11/08)
 - 05/06/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/11/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 01/11/08 [CR09]
- Primary Reviews
 - 07/02/09: Primary Reviewer 1 Comments
- Support Documents
 - 01/09/09: DMC Minutes
 - January 2009-Study Summary

RTOG-0436

Continuing Review (CR): Continuing Review July 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/13/09)
- Correspondence
 - 07/09/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/13/09)
 - 05/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 02/13/09



- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 02/13/09 [CR09]
- Primary Reviews
 - 07/02/09: Primary Reviewer 1 Comments
- Support Documents
 - June 2009 Study Summary
 - 01/09/09: DMC Minutes

Pediatric Studies

COG-AREN0534

Continuing Review (CR): Continuing Review January 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/15/08)
- Correspondence
 - 01/13/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/15/08)
 - 10/06/08: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/15/08

Serious Adverse Events Posted

Adult Studies

Study Number

Study: CALGB 100104
SAE Posted: 1358268 FU1, 1628411

Study: CALGB 40302
SAE Posted: 000704, Z0000646A

Study: CALGB 40502



SAE Posted: 1034535 FU1, 1277486, 1314985, 1433885 FU1, 1809441, 1951869 FU2, 1987521, 1994045, 1034535,1160914,1201753,1324148 FU1, 1360351, 1951869 FU1,CA031-09-0088

Study: CALGB 40503

SAE Posted: 1034535 FU1, 1277486, 1314985, 1433885 FU1, 1809441, 1951869 FU2, 1987521, 1994045, 1034535, 1201753, 1324148 Fu1, 1360351, 1951869 FU1

Study: CALGB 80203

SAE Posted: 09-02-16203 FU2, 09-02-16435 FU3, 09-02-16482, 09-02-16603 FU1

Study: CALGB 80303

SAE Posted: 1034535, 1034535 FU1, 1201753, 1277486, 1314985, 1324148 FU1, 1360351, 1433885 FU1, 1809441, 1951869 FU1, 1951869 FU2, 1987521, 1994045

Study: CALGB 80405

SAE Posted: 09-02-16203 FU2, 09-02-16435 FU3, 09-02-16482, 09-02-16603 FU1, 1034535, 1034535 FU1, 1201753, 1277486, 1314985, 1324148 FU1, 1360351, 1433885 FU1, 1809441, 1951869 FU1, 1951869 FU2, 1987521, 1994045

Study: CALGB 90206

SAE Posted: 1034535, 1034535 FU1, 1201753, 1277486, 1314985, 1324148 FU1, 1360351, 1433885 FU1, 1809441, 1951869 FU1, 1951869 FU2, 1987521, 1994045, 273064

Study: CALGB 90401

SAE Posted: 1034535, 1034535 FU1, 1201753, 1277486, 1314985, 1324148 FU1, 1360351, 1433885 FU1, 1809441, 1951869 FU1, 1951869 FU2, 1987521, 1994045

Study: ECOG E1105

SAE Posted: 273064

Study: ECOG E1305

SAE Posted: 1034535, 1133874, 1201753, 1293580, 1324148 FU1, 1329128, 1360351, 1391765, 1419144, 1433885 FU1, 1475911 FU1, 1580693 FU1, 1836781, 1951869 FU1

Study: ECOG E1505

SAE Posted: 1133874, 1293580, 1329128, 1391765, 1419144, 1836781,



Study: GOG 0213
SAE Posted: 1433885 FU1

Study: GOG 0218
SAE Posted: 1201753 FU1, 1433885 FU1, 1833568

Study: GOG 0219
SAE Posted: 1219411, 1219411 FU1

Study: GOG 0240
SAE Posted: 1034535 FU1, 1133874, 1201753 FU1, 1277486, 1293580, 1314985, 1329128, 1391765, 1419144, 1809441, 1833568, 1836781, 1987521, 1994045

Study: NSABP B-34
SAE Posted: 200910081 SU116 FU1, 200916901 SU127, 200917399 SU128, DE-2006-032513 SU 41 FU5

Study: NSABP B-38
SAE Posted: DE200702001788 FU2, DE200902001955, DE200902002200, DE200902002201, DE200904000693, FR200806005794 FU1, FR200902003893, FR200902003893 FU1, FR200903000570, JP200812005805, JP200812005805 FU1, JP200903004313, NL200811000680, US200605004414, US200904002663

Study: NSABP B-40
SAE Posted: DE200904000693, FR200902003893 FU1, JP200903004313, US200904002663

Study: NSABP C-08
SAE Posted: 1034535, 1034535 FU1, 1201753, 1314985, 1324148, 1324148 FU1, 1360351, 1433885 FU1, 1475911 FU1, 1809441, 1881593, 1951869 FU2, 1987521, 1994045, 1996104

Study: NSABP R-04
SAE Posted: 1201753

Study: RTOG 0617
SAE Posted: 08-02-15483 FU1, 08-02-15541 FU3, 08-02-15660 FU2, 08-02-15765 FU2, 08-02-15831 FU1, 09-02-15897 FU2, 09-02-15898, 09-02-15898 FU1, 09-02-15929 FU1, 09-02-15929 FU2, 09-02-15973 FU1, 09-02-15982, 09-02-16124 FU1, 09-02-16124 FU2, 09-02-16130 FU1, 09-02-16130 FU2, 09-02-16131, 09-02-16131 Fu1, 09-02-16296 FU1, 09-02-16306, 09-02-16306 FU1, 09-02-16382 FU1, 09-02-16435 FU2, 09-02-16435 FU3, 09-02-16468 FU1, 09-02-



16476 FU1, 09-02-16481 FU1, 09-02-16482, 09-02-16601, 09-02-16746, 09-02-16791

Pediatric Studies

None

Corrections to Previous Postings

Adult Studies

ECOG-E5103

Documents Posted: 05/21/09 Change Memo (Protocol Version Date 05/21/09)

Correction: 05/21/09 Change Memo was posted to the NCI CIRB web to reflect the current protocol version date of the protocol and the current informed consent document

NSABP B-40

Documents Posted: **CIRB Acknowledgement Updated Bevacizumab Investigator's Brochure**

Correction: The July 1, 2009 Website Postings Summary contains the following error: The 06/17/09 CIRB Acknowledgement Letter incorrectly identifies NSABP B-35 instead of B-40.

- 06/17/09: CIRB Acknowledgement of NSABP B-40 Updated Bevacizumab Investigator's Brochure Version 16

Pediatric Studies

None

If review of this Website Postings Summary has prompted any questions, please forward them to the NCI CIRB_Operations Office Helpdesk at NCICIRBContact@emmes.com or call the CIRB HelpDesk toll-free at 888-657-3711.