



NCI Central IRB Website Postings Summary October 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

- NONE
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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

- None



Posted Documents Related to Amendment Reviews:

Adult Studies

ACOSOG-Z1031

****Re-Open to Accrual – Effective October 1, 2009****

Amendment Review (AR): Amendment #6 (Protocol Version Date 08/26/09)

Documents Posted:

- Amendments
 - 08/26/09: ACOSOG Change Memo (Protocol Version Date 08/26/09)

- CIRB Application
 - CIRB Application (Protocol Version Date 08/26/09)
 - CIRB Application (Protocol Version Date 07/13/09)
 - CIRB Application (Protocol Version Date 05/06/09)

- Correspondence
 - 10/01/09: CIRB Acknowledgement - Amendment 6 Activation and Reopening to Accrual Memo dated 10/1/09
 - 10/01/09: ACOSOG Amendment 6 Activation Memo
 - 09/09/09: CIRB Approval Letter Amendment 6 (Final Revisions) (Protocol Version Date 08/26/09)
 - 08/11/09: CIRB Approval Letter Amendment 6 (Protocol Version Date 07/13/09)
 - 07/08/09: CIRB Approval Pending Modifications Letter Amendment 6 (Protocol Version Date 05/06/09)

- Protocol
 - Protocol Version Date 08/26/09
 - Protocol Version Date 08/26/09 Highlighted
 - Protocol Version Date 07/13/09
 - Protocol Version Date 07/13/09 Highlighted
 - Protocol Version Date 05/06/09
 - Protocol Version Date 05/06/09 Highlighted

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/26/09 [Am6]: Cohort A
 - CIRB's Informed Consent Document for Protocol Version Date 08/26/09 [Am6]: Cohort B
 - CIRB's Informed Consent Document for Protocol Version Date 08/26/09 [Am6]: Genome
 - CIRB's Informed Consent Document for Protocol Version Date 08/26/09 [Am6]: Tissue



- Primary Reviews
 - 08/06/09: Primary Reviewer 1 Comments
 - 06/18/08: Primary Reviewer 1 Comments

- Minutes
 - 08/06/09: Minutes - Amendment 6 Review
 - 06/18/09: Minutes - Amendment 6 Review

ECOG-E4A03

Amendment Review (AR): Addendum #8 (Protocol Version Date 09/03/09)

Documents Posted:

- Amendments
 - 09/03/09: ECOG Change Memo (Protocol Version Date 09/03/09)

- CIRB Application
 - CIRB Application (Protocol Version Date 09/03/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/03/09)

- Correspondence
 - 09/08/09: CIRB Addendum 8 Approval Letter (Protocol Version Date 09/03/09)

- Protocol
 - Protocol Version Date 09/03/09

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/03/09 [Add8]

ECOG-E2805

Amendment Review (AR): CIRB Acknowledgement - Technetium 99 Shortage Memo dated June 05, 2009

Documents Posted:

- Correspondence
 - 10/06/09: CIRB Acknowledgement - Technetium 99 Shortage Memo dated June 05, 2009
 - 06/05/09: ECOG E2805 Technetium 99 Shortage Memo

ECOG-E5103

****Enrollment SUSPENSION – Effective September 24, 2009****

Amendment Review (AR): CIRB Acknowledgement - Study Suspension



Documents Posted:

- Correspondence
 - 10/07/09: CIRB Acknowledgment of E5103 Study Suspension
 - 09/24/09: ECOG Protocol Suspension Notice EFFECTIVE September 24, 2009

Amendment Review (AR): CIRB Acknowledgement - Dear Participant and Dear Physician Letters

Documents Posted:

- Correspondence
 - 10/09/09: CIRB Acknowledgement - Dear Participant and Dear Physician Memos
- Support Documents
 - Dear Participant Memo with Signature
 - Dear Participant Memo
 - Dear Physician Memo

GOG-0249

Amendment Review (AR): Revision #4 (Protocol Version Date 09/11/09)

Documents Posted:

- Amendments
 - 09/11/09: GOG Change Memo (Protocol Version Date 09/11/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 09/11/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 09/11/09)
- Correspondence
 - 09/17/09: CIRB Revision 4 Approval Letter (Protocol Version Date 09/11/09)
- Protocol
 - Protocol Version Date 09/11/09
 - Protocol Version Date 09/11/09 - Highlighted Changes
 - Appendix I: Clinical Staging - Carcinoma of the Corpus Uteri
 - Appendix II: Specimen Procedures
 - Appendix III: Logistical Guidelines
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/11/09 [Rev4]



NSABP-B-42

Amendment Review (AR): CIRB Acknowledgement - Recall and Resupply Drug Supply (Letrozole/Placebo) Memo dated 09/21/09

Documents Posted:

- Correspondence
 - 09/30/09: CIRB Acknowledgement of NSABP B-42 Recall and Resupply of Drug Supply (Letrozole/Placebo) Memo dated September 21, 2009

RTOG-0825

Amendment Review (AR): Update 09/29/09 (Protocol Version Date 08/27/09)

Documents Posted:

- Amendments
 - 09/29/09: RTOG Change Memo (Protocol Version Date 08/27/09)
- Correspondence
 - 10/07/09: CIRB Update 09/29/09 Approval Letter (Protocol Version Date 08/27/09)
- Protocol
 - Protocol Version Date 08/27/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/27/09 [up092909]

Amendment Review (AR): Amendment #2 (Protocol Version Date 08/27/09)

Documents Posted:

- Amendments
 - 08/27/09: Change Memo (Protocol Version 08/27/09)
- CIRB Application
 - CIRB Application (Protocol Version 08/27/09)
 - Summary of CIRB Application Revisions (Protocol Version 08/27/09)
- Correspondence
 - 09/14/09: CIRB Amendment 2 Approval Letter (Protocol Version 08/27/09)
 - 08/27/09: RTOG Cover Memo
- Protocol
 - Protocol Version Date 08/27/09



- Protocol Version Date 08/27/09 - Highlighted Changes
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/27/09 [Am2]

Amendment Review (AR): Amendment #1 (Protocol Version Date 07/20/09)

Documents Posted:

- Amendments
 - 07/20/09: Change Memo (Protocol Version Date 07/20/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 07/20/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/20/09)
- Correspondence
 - 08/04/09: CIRB Amendment 1 Approval Letter (Protocol Version Date 07/20/09)
 - 07/20/09: RTOG Cover Memo
- Protocol
 - Protocol Version Date 07/20/09
 - Protocol Version Date 07/20/09 - Highlighted Changes
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/20/09 [Am1]

SWOG-S0777

Amendment Review (AR): Revision #4 (Protocol Version Date 07/15/09)

Documents Posted:

- Amendments
 - 07/15/09: SWOG Change Memo (Protocol Version Date 07/15/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 07/15/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/15/09)
- Correspondence
 - 07/23/09: CIRB Revision 4 Approval Letter (Protocol Version Date 07/15/09)



- Protocol
 - Protocol Version Date 07/15/09

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/15/09 [Rev4]
 - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 07/15/09 [Rev4]

Pediatric Studies

COG-AALL0622

****Temporarily Closed to Accrual by COG - Effective October 2, 2009****

Amendment Review (AR): **Acknowledgement of AALL0622 Study Temporary Closure to Accrual (10/02/09)**

Documents Posted:

- Correspondence
 - 10/08/09: CIRB Acknowledgement-Temporary Closure to Accrual
 - 10/05/09: COG Notice-Temporary Closure to Accrual

COG-AAML0523

****Study Reactivation by COG - Effective October 5, 2009****

Amendment Review (AR): **Amendment #2A (Protocol Version Date 09/17/2009)**

Documents Posted:

- Amendments
 - 08/19/09: Change Memo (Protocol Version Date 08/19/09) [NOTE: Changes noted in this memo for Amendment #2 (Protocol Version Date 08/19/09) are incorporated in Amendment #2A]
 - 09/17/09: COG Change Memo (Protocol Version Date 09/17/09)

- CIRB Application
 - CIRB Application (Protocol Version Date 09/17/09)

- Correspondence
 - 10/05/09: COG-AAML0523 Amendment #2A Reactivation Memo
 - 09/23/09: CIRB Final Approval of COG-AAML0523 Amendment #2A (Protocol Version Date 09/17/09)

- Protocol
 - Protocol Version Date 09/17/09
 - Protocol Version Date 09/17/09 - Highlighted Changes



- Informed Consent
 - Informed Consent Document for Protocol Version Date 09/17/09
- Primary Reviews
 - 09/10/09: Primary Reviewer 1 Comments

COG-ADVL0821

****Partial Closure for Disease Strata: Neuroblastoma Stratum and Second-stage Accrual for the Rhabdomyosarcoma Stratum -- Effective October 9, 2009****

Amendment Review (AR): **Partial Closure for ADVL0821 - Disease Strata: Neuroblastoma Stratum and Second-stage -- (10/09/09)**

Documents Posted:

- Correspondence
 - 10/12/09: CIRB Acknowledgement - Partial Closure for Neuroblastoma (MIBG+ without Measure Disease) and Rhabdomyosarcoma
 - 10/09/09: COG Notice - Partial Closure for Neuroblastoma (MIBG+ without Measure Disease) and Rhabdomyosarcoma

COG-AREN0532

Amendment Review (AR): **CIRB Acknowledgment of AREN0532 Amendment #3 Protocol and Informed Consent Document Corrections**

Documents Posted:

- Correspondence
 - 10/09/09: CIRB Acknowledgment of AREN0532 Amendment #3 Protocol and Informed Consent Document Corrections
 - 09/18/09: COG Corrections to protocol and informed consent forms for AREN0532 Amendment #3 (06/05/09)

Posted Documents Related to Continuing Reviews:

Adult Studies

CALGB-10501

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 12/10/08)
- Correspondence
 - 10/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 12/10/08)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 12/10/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 12/10/09 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments
- Support Documents
 - 06/26/09: DSMB Meeting
 - June 2009 - Study Summary

CALGB-10603

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/06/09)
- Correspondence
 - 10/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/06/09)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 02/06/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 02/06/09 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments
- Support Documents



- 06/26/09: DSMB Meeting
- June 2009 - Study Summary

CALGB-30610

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 10/28/08)
- Correspondence
 - 10/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/28/08)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 10/28/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 10/28/08 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments
- Support Documents
 - 06/26/09 DSMB Meeting
 - June2009 – Study Summary

ECOG-E5103

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 07/16/09)
- Correspondence
 - 10/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 07/16/09)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 07/16/09



- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/16/09 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments
- Support Documents
 - June 2009 - Study Summary
 - April 2009 - DMC Recommendations

NCIC CTG-PR.11

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Correspondence
 - 10/08/09: CIRB Acknowledgement of NCIC CTG PR.11 Response to Continuing Review 2009 Query
 - 10/05/09: NCIC CTG Response to PR.11 Continuing Review 2009 Memo

Additional documents associated with this action have been previously posted to the Website Posting Summary and are available on the website.

RTOG-0617

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 03/09/09)
- Correspondence
 - 10/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/09/09)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 03/09/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/09/09 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments



- Support Documents
 - 06/05/09: DMC Minutes
 - June 2009 - Study Summary

RTOG-0825

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 08/27/09)
- Correspondence
 - 10/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/27/09)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 08/27/09
 - Protocol Version Date 08/27/09 - Highlighted Changes
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 08/27/09 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments
- Support Documents
 - 06/05/09: DMC Minutes
 - June 2009 - Study Summary

SWOG-S0106

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 03/28/08)
- Correspondence
 - 10/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/08)
 - 08/04/09: Continuing Review Reminder Notice S0106



- Protocol
 - Protocol Version Date 03/28/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/28/08 [CR09]
- Primary Reviews
 - 10/01/09: Primary Reviewer 1 Comments
- Support Documents
 - 08/11/09: DSMC Minutes
 - April 2009 - Study Summary

SWOG-S0124

Continuing Review (CR): Continuing Review October 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/29/07)
- Correspondence
 - 10/08/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/29/07)
 - 08/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/29/07
- Support Documents
 - 05/02/08: Minutes of DSMC Meeting
 - May 2009 - Study Summary

Pediatric Studies

- None

Serious Adverse Events Posted

Adult Studies

Study Number

CALGB-90601



SAEs posted:

1133874 FU1
1202538
1232396 FU1
1257729
1257729 FU1
1293580 FU1
1314985 FU1
1329128 FU1
1360351 FU1
1390754 FU1
1613977
1687519
1809441 FU1
1881593 FU1
1987521 FU1

ECOG E1505

SAEs posted:

1158823 FU1
1192440
1201753 FU1
1202538
1232396
1232396 FU1
1257729
1257729 FU1
1333814
1360351 FU1
1390754
1390754 FU1
1392926
1687519
1718620 and 1718620 FU1 (corrected report)
1833568
1881593 FU1
1950915
1968432 FU1
1987521 FU1

ECOG E5202



SAEs posted:

1133874 FU1
1158823 FU1
1192440
1201753 FU1
1202538
1232396
1257729
1265048
1333814
1360351 FU1
1390754
1390754 FU1
1392926
1687519
1809441 FU1
1833568
1839475
1881593 FU1
1950915
1968432 FU1
1987521 FU1

ECOG E5204

SAEs posted:

1158823 FU1
1192440
1201753 FU1
1202538
1232396
1232396 FU1
1257729
1257729 FU1
1265048
1265048 FU1
1333814
1360351 FU1
1390754
1390754 FU1
1392926
1687519
1718620 and 1718620 FU1 (corrected report)
1833568



1881593 FU1
1950915
1968432 FU1
1987521 FU1

GOG 0213

SAEs posted:

1158823 FU1
1192440
1201753 FU1
1232396
1232396 FU1
1257729
1257729 FU1
1333814
1360351 FU1
1390754
1390754 FU1
1392926
1718620
1718620 FU1
1833568
1950915
1968432 FU1

GOG 0252

SAEs posted:

1232396 FU1
1293580 FU1
1438181 FU2
1613977

NCCTG N0147

SAEs posted:

09-02-16834
09-02-17429 FU1
09-02-17430 FU1
1265048 FU1

NSABP R-04

SAEs posted:



SU 404-NCI-87_1265048
SU 405-NCI-88_1201753 Fu1
SU 406-NCI-89_1265048 FU1

SWOG S0777

SAEs posted:

1203812 FU2
1358268 FU1
1567424 FU1
1871314

Pediatric Studies

Study Number

COG AALL0622

SAEs Posted:

1263182
1519074

COG AALL0631

SAEs Posted:

20090006958
2009002712
2009003210
2009008223
2009008405
US025340 FU3

COG AALL07P4

SAEs posted:

2009EN000219
2009EN000010 FU5
2009EN000047 FU3
2009EN000047 FU4
2009EN000117 FU3



2009EN000146 FU2
2009EN000149 FU2
2009EN000150
2009EN000167 FU1
2009EN000167 FU2
2009EN000181 FU1
2009EN000190
2009EN000190 FU1
2009EN000202
2009EN000210
2009EN000219
2009EN000225

COG AAML06P1

SAEs posted:

2009002712
2009003210
2009006958
2009008223
2009008405
US025340 FU3

COG AAML07P1

SAEs posted:

1673759 FU1 corrected

COG ACNS0621

SAEs posted:

6050234 FU1

COG ADVL0221

SAEs posted:

CH-JNJFOC-20090404158 FU4
IN-JNJFOC-20090301053 FU6
IN-JNJFOC-20090302921 FU6
LU-JNJFOC-20090402112 FU1
PT-JNJFOC-20090606395
US-JNJFOC-20031001879 FU4
US-JNJFOC-20080403865 FU5



US-JNJFOC-20081204254 FU3
US-JNJFOC-20090102891 FU4
US-JNJFOC-20090105236 FU2
US-JNJFOC-20090106668 FU2
US-JNJFOC-20090201807 FU2
US-JNJFOC-20090700850 FU1
US-JNJFOC-20090705550
US-JNJFOC-20090706110
ZA-JNJFOC-20080602469 FU3

COG ADVL0821

SAEs posted:

09-12-00163
09-12-00163 FU1
09-12-00168 FU1
09-12-00205 - DDL 037
09-13-00110 FU1
09-13-00138
09-13-00141
09-13-00141 FU1
09-13-00161
09-13-00161 FU1 - DDL 030 FU1
09-13-00173 - DDL 035
09-13-00174 FU1 - DDL 036
1087351
1875844

COG AEWS0521

SAEs posted:

1232396 FU1
1257729 FU1
1293580 FU1
1329128 FU1
1613977
1994045 FU1

Corrections to Previous Postings



Adult Studies

- NONE

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 1-(888) 657-3711.