



NCI Central IRB Website Postings Summary

September 1, 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

Documents Posted:

- NONE

Pediatric Studies

Documents Posted:

- NONE



Posted Documents Related to Amendment Reviews:

Adult Studies

ECOG-E2805

Amendment Review: Addendum #7 (Protocol Version Date 07/17/09)

Documents Posted:

- Amendments
 - 07/17/09 Change Memo (Protocol Version Date 07/17/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 07/17/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/17/09)
- Correspondence
 - 08/13/09: ECOG Activation Notice
 - 08/07/09: CIRB Approval Letter Addendum 7 (Protocol Version Date 07/17/09)
- Protocol
 - Protocol Version Date 07/17/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/17/09 [Add7]
- Primary Reviews
 - 08/06/09: Primary Reviewer 1 Comments

ECOG-E5202

Amendment Review: CIRB Acknowledgement - Notification of Re-Opening to Accrual Effective August 10, 2009

Documents Posted:

- Correspondence
 - 08/20/09: Acknowledgement of Re-Open to Accrual
 - 08/10/09: Re-Open to Accrual

ECOG-E5204

Amendment Review: Addendum #4 (Protocol Version Date 07/17/09)

Documents Posted:

- Amendments
 - 07/17/09: Change Memo (Protocol Version Date 07/17/09)



- Correspondence
 - 08/07/09: CIRB Approval Letter Addendum 4 (Protocol Version Date 07/17/09)
- Protocol
 - Protocol Version Date 07/17/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/17/09 [Add4]
- Primary Reviews
 - 08/06/09: Primary Reviewer 1 Comments

CALGB-40503

Amendment Review: Update #1 (Protocol Version Date 06/23/09)

Documents Posted:

- Amendments
 - Change Memo
- CIRB Application
 - CIRB Application (Protocol Version Date 06/23/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/23/09)
- Correspondence
 - 08/12/09: CIRB Update 1 Approval Letter (Protocol Version Date 06/23/09)
- Support Documents
 - Healthcare Professional Questionnaire
 - Patient Questionnaire
- Protocol
 - Protocol Version Date 06/23/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/23/09 [Up1]
- Primary Reviews
 - 08/06/09: Primary Reviewer 1 Comments



CALGB-100104

Amendment Review: Update #8 (Protocol Version Date 07/01/09)

Documents Posted

- Amendments
 - 08/15/09: Change Memo (Protocol Version Date 07/01/09)
- Correspondence
 - 08/12/09: CIRB Update 8 Approval Letter (Protocol Version Date 07/01/09)
- Protocol
 - Protocol Version Date 07/01/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/01/09 [Up8]
- Primary Reviews
 - 08/06/09: Primary Reviewer 1 Comments

CALGB-140503

Amendment Review: Update #3 (Protocol Version date 06/30/09)

Documents Posted

- Amendments
 - 08/15/09: Change Memo (Protocol Version Date 06/30/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 06/30/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/30/09)
- Correspondence
 - 07/20/09: CIRB Update 3 Approval Letter (Protocol Version Date 06/30/09)
- Protocol
 - Protocol Version Date 06/30/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/30/09 [Up3]



- Primary Reviews
 - 07/16/09: Primary Reviewer 1 Comments

GOG-0218

****Closed to Accrual – Effective August 10, 2009****

Amendment Review: CIRB Acknowledgement - Closure to Accrual – Effective August 10, 2009

Documents Posted:

- Correspondence
 - 08/21/09: CIRB Acknowledgement of GOG Notification of Closure to Accrual
 - 08/10/09: GOG Notification of Closure of Accrual

GOG-0219

****Upcoming Study Suspension on September 1, 2009****

GOG-0258

Amendment Review: CIRB Activation Amendment Notice

Documents Posted:

- Correspondence
 - CIRB Review of GOG 0258 Revision #2 (Protocol Version Date 08/05/09)

NCCTG-N06C6

Amendment Review: Addendum #2 (Protocol Version Date 07/01/09)

Documents Posted:

- Amendments
 - 07/01/09: Change Memo (Protocol Version Date 07/01/09)
- Correspondence
 - 07/23/09: CIRB Addendum 2 Approval Letter (Protocol Version Date 07/01/09)
- Protocol
 - Protocol Version Date 07/01/09
 - Protocol Version Date 07/01/09 (Highlighted)
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/01/09 [Add2]
 - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 07/01/09 [Add2]



NCCTG-N0147

Amendment Review: CIRB Acknowledgement - Request Letter for KRAS Test Results

Documents Posted:

- Correspondence
 - 08/18/09: CIRB Acknowledgment of Receipt of KRAS Request Letter
 - 08/06/09: Request Letter for KRAS Test

NSABP-B-35

Amendment Review: Amendment #5 (Protocol Version Date 07/17/09)

Documents Posted:

- Amendments
 - Change Memo (Protocol Version Date 07/17/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 07/17/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/17/09)
- Correspondence
 - 08/07/09: CIRB Amendment 5 Approval Letter (Protocol Version Date 07/17/09)
- Protocol
 - Protocol Version Date 07/17/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/17/09 [Amd5]

NSABP-B-40

Amendment Review: CIRB Acknowledgement - Guidance for Avoiding Excess Toxicity Memo

Documents Posted:

- Correspondence
 - 08/25/09: CIRB Acknowledgement of NSABP B-40 Guidance For Avoiding Excess Toxicity Memo
 - 08/06/09: NSABP B-40 Guidance For Avoiding Excess Toxicity

RTOG-0521

****Closed to Accrual – Effective August 21, 2009****

Amendment Review: Closure to Accrual – Effective August 21, 2009 (**Informed Consent Documents updated with closure text**)



Amendment Review: Amendment #5 (Protocol Version Date 07/28/09)

Documents Posted:

- Amendments
 - 07/28/09: Change Memo (Protocol Version Date 07/28/09)

- CIRB Application
 - CIRB Application (Protocol Version Date 07/28/09)
 - CIRB Application (Protocol Version Date 07/28/09) - Highlighted Changes
 - Summary of CIRB Application Revisions (Protocol Version Date 07/28/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 07/28/09) - Highlighted Changes

- Correspondence
 - 08/13/09: CIRB Amendment 5 Approval Letter (Protocol Version Date 07/28/09)
 - 07/28/09: RTOG Cover Memo

- Protocol
 - Protocol Version Date 07/28/09
 - Protocol Version Date 07/28/09 - Highlighted Changes

- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/28/09 [Am5]
 - CIRB's Informed Consent Document for Protocol Version Date 07/28/09: Tissue

SWOG-S0106

****Closed to Accrual – Effective August 20, 2009****

Amendment Review: Closure to Accrual – Effective August 20, 2009 (**Informed Consent Document updated with closure text**)

SWOG-S0307

Amendment Review: CIRB Approval with Query - Clodronate Shortage

Documents Posted:

- Correspondence
 - 08/13/09: CIRB Approval with Query of Clodronate Shortage
 - 06/01/09: Clodronate Shortage Memo



SWOG-S0819

Amendment Review: 08/12/09: C-Pirat Activation Amendment Notice

Documents Posted:

- Correspondence
 - CIRB Review of SWOG S0819 Revision #1 (Protocol Version Date 07/29/09)

Pediatric Studies

COG-AALL0434

**** Closure of PK Portion of AALL0434 Study – Effective August 21, 2009****

Amendment Review (AR): **Acknowledgement of Closure of PK Portion of AALL0434 Study**

Documents Posted:

- Correspondence
 - 08/21/09: CIRB Acknowledgement of Closure of PK Portion of AALL0434 Study
 - 08/21/09: COG Memo - Closure of PK Portion of AALL0434 Study

COG-AALL0631

****Study Re-Activation by COG - Effective August 24, 2009****

Amendment Review (AR): Amendment #1A and Reactivation (Protocol Version Date 07/08/2009)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 07/08/09)
 - CIRB Application (Protocol Version Date 05/19/09)
- Correspondence
 - 08/24/09: COG AALL0631 Amendment #1A Reactivation Memo
 - 08/18/09: CIRB Approval of COG AALL0631 Amendment #1A (Protocol Version Date 07/08/09)
 - 07/08/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/19/09)
 - 06/25/09: CIRB Approval Pending Modification Letter (Protocol Version Date 05/19/09)
 - 05/19/09: COG Change Memo (Protocol Version Date 05/19/09)
- Protocol
 - Protocol Version Date 07/08/09



- Protocol Version Date 07/08/09 - Highlighted Changes
- Protocol Version Date 05/19/09
- Protocol Version Date 05/19/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document for Protocol Version Date 07/08/09 - Part 1 Phase 1
 - Informed Consent Document for Protocol Version Date 07/08/09 - Part 1 Non-Phase 1
 - Informed Consent Document for Protocol Version Date 07/08/09 - Part 2

- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments

- Minutes
 - 06/11/09: Minutes - Amendment Review

COG-AALL06N1

Amendment Review (AR): Amendment #2 (Protocol Version Date 07/08/09)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 07/08/09)

- Correspondence
 - 08/17/09: COG AALL06N1 Amendment #2 Activation Memo
 - 08/04/09: CIRB Approval of COG AALL06N1 Amendment #2 (Protocol Version Date 07/08/09)
 - 07/08/09: COG Change Memo (Protocol Version Date 07/08/09)

- Protocol
 - Protocol Version Date 07/08/09
 - Protocol Version Date 07/08/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document For Protocol Version Date 07/08/09 - Sites Participating In MRI With DTI Project
 - Informed Consent Document For Protocol Version Date 07/08/09 - Sites NOT Participating In MRI With DTI Project

COG-AAML0531

Amendment Review (AR): Amendment #2 (Protocol Version Date 07/14/2009)

Documents Posted:

- CIRB Application



- CIRB Application (Protocol Version Date 07/14/09)
- Correspondence
 - 08/24/09: COG AAML0531 Amendment #2 Activation Memo
 - 08/18/09: CIRB Approval of COG AAML0531 Amendment #2 (Protocol Version Date 07/14/09)
 - 07/14/09: COG Change Memo (Protocol Version Date 07/14/09)
- Protocol
 - Protocol Version Date 07/14/09
 - Protocol Version Date 07/14/09 - Highlighted Changes
- Informed Consent
 - Informed Consent Document for Protocol Version Date 07/14/09 - Parental Permission
 - Informed Consent Document for Protocol Version Date 07/14/09 - Additional Bone Marrow

COG-ACCL0631

****Closed to Accrual by COG - Effective August 17, 2009****

Amendment Review (AR): **Acknowledgement of ACCL0631 Study Closure (08/17/09)**

Documents Posted:

- Correspondence
 - 08/17/09: CIRB Acknowledgement of COG ACCL0631 Closure to Accrual
 - 08/17/09: COG Memo - Closure of ACCL0631
- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/30/09

COG-ADVL0525

****Partial Closure for Neuroblastoma Disease Strata – Effective July 30, 2009****

Amendment Review (AR): **Acknowledgement of COG ADVL0525 Partial Closure for Neuroblastoma Disease Strata (07/30/09)**

Documents Posted:

- Correspondence
 - 08/17/09: CIRB Acknowledgement: ADVL0525 Partial Closure for Neuroblastoma Disease Strata
 - 07/30/09: COG Notice: ADVL0525 Partial Closure for Neuroblastoma Disease Strata



COG-ADVL0821

****Reactivation of Accrual for Ten Additional Patients for Rhabdomyosarcoma Stratum - Effective August 19, 2009****

Amendment Review (AR): **Acknowledgement of COG ADVL0821 Reactivation of Accrual for Ten Additional Patients for Rhabdomyosarcoma Stratum (8/19/09)**

Documents Posted:

- Correspondence
 - 08/21/09: CIRB Acknowledgement - Re-opening of the Rhabdomyosarcoma Stratum to Accrual
 - 08/19/09: COG Notice - ADVL0821 Re-opening of the Rhabdomyosarcoma Stratum to Accrual

COG-AEWS0521

****Reactivation of Accrual for Ten Additional Patients for Rhabdomyosarcoma Stratum - Effective August 19, 2009****

Amendment Review (AR): **Acknowledgement of COG-AEWS0521 Closure to Accrual (08/21/09)**

Documents Posted:

- Correspondence
 - 08/21/09: CIRB Acknowledgement of COG AEWS0521 Closure to Accrual
 - 08/21/09: COG Memo - AEWS0521 Closure to Accrual
- Informed Consent
 - Informed Consent Document for Protocol Version Date 10/13/08 - Feasibility
 - Informed Consent Document for Protocol Version Date 10/13/08 - Randomized Study

Posted Documents Related to Continuing Reviews:

Adult Studies

NSABP-B-42

Continuing Review: Continuing Review June 2009

Documents Posted:

- Correspondence
 - 08/14/09: CIRB Acknowledgement of Query Response



- 06/30/09: NSABP Response to CIRB Query

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

Pediatric Studies

COG-AAML0631

Continuing Review (CR): Continuing Review August 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/14/09)
- Correspondence
 - 08/17/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/14/09)
 - 07/06/09: CIRB Continuing Review Reminder Notice
- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/14/09 - BONE MARROW
 - Informed Consent Document for Protocol Version Date 01/14/09 - PARENTAL PERMISSION

COG-ALTE05N1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Correspondence
 - 08/14/09: Correction to ALTE05N1 Approval Outcome Letter
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/15/09) - CORRECTION

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.



Serious Adverse Events Posted

Adult Studies

Study Number

ACOSOG Z1031

SAE Posted:

1726306 FU4

CALGB 40502

SAE Posted:

1160914 FU1

CALGB 40601

SAEs Posted:

1353951

B0567619A FU1

ECOG E2902

SAEs Posted:

1320161

1320161 FU1

1364650 FU1

ECOG E2905

SAEs Posted:

1203233

1277486

1628411

1673759

1673759 FU1



RTOG 0617

SAEs Posted:

09-02-16049 FU1
09-02-16049 FU2

SWOG S0307

SAEs Posted:

200911902 SU137
200911902 SU137 FU1
200913597 SU120 FU1
200913597 SU120 Fu2
200920427 SU134
200920427 SU134 FU1
200922309 SU138

SWOG S0502

SAEs Posted:

1034535
1034535 Fu1
1133874
1158823 Fu1
1192440
1201753
1201753 FU1
1202538
1232396
1257729
1277486
1293580
1314985
1324148 FU1
1329128
1333814
1360351
1360351 FU1
1390754
1390754 FU1
1391765
1392926
1419144



1433885 Fu1
1475911 FU1
1580693 FU1
1718620
1718620 FU1
1809441
1833568
1836781
1881593 FU1
1950915
1951869 FU1
1951869 FU2
1968432 Fu1
1987521
1987521 FU1
1994045
1996104
273064

Pediatric Studies

Study Number

COG AALL07P4

SAEs Posted:

2009EN000010 FU4
2009EN000131 FU1
2009EN000131 FU2
2009EN000143
2009EN000143 FU1
2009EN000146
2009EN000146 Fu1
2009EN000147
2009EN000147 FU1
2009EN000149
2009EN000149 FU1
2009EN000150 FU1
2009EN000167
2009EN000181



COG ADVL0221

SAEs posted:

**IN-JNJFOC-20090302921 FU2
IN-JNJFOC-20090302921 FU4
LU-JNJFOC-20090402112
US-JNJFOC-20080400179 Fu7
US-JNJFOC-20080502379 FU4
US-JNJFOC-20090100065 FU4
US-JNJFOC-20090102891 FU3**

COG ADVL0525

SAEs posted:

**FR200901005537
MX200904002967
MX200904002967 FU1
MX200904005930
MX200904005930 FU1
US200904005208
US200904005208 FU1**

COG AEWS0521

SAEs posted:

**1034535 FU1
1133874
1133874 FU1
1192440
1201753 FU1
1232396
1257729
1293580
1314985
1329128
1333814
1360351 FU1
1390754
1390754 FU1**



Corrections to Previous Postings

Adult Studies

Documents Posted:

Correction:

- None

Pediatric Studies

Documents Posted:

Correction:

- 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.