



**NCI Central IRB Study Activity Update
October 31, 2008**

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. **



New Initial Approvals Posted:

The new studies listed below have received CIRB approval and are entitled to facilitated review at your local IRB as part of the NCI CIRB initiative. You can download a completed application from the CIRB website along with the documents specified by your local IRB.

Adult CIRB Studies

CALGB-40502

Initial Review (IR) 2008 Approval Protocol Version Date 09/04/08

Documents Posted:

- Protocol Version Date 09/04/08
- Protocol Version Date 07/10/08
- Protocol Version Date 03/20/08
- Informed Consent Document for Protocol Version Date 09/04/08
- CIRB Application (Protocol Version Date 09/04/08)
- Summary of CIRB Application Revisions (Protocol Version Date 09/04/08)
- CIRB Application (Protocol Version Date 07/10/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/10/08)
- CIRB Application (Protocol Version Date 03/20/08)
- 05/19/08: Primary Reviewer 1 Comments
- 05/19/08: Primary Reviewer 2 Comments
- 05/19/08: Primary Reviewer 3 Comments
- 10/13/08: Group Activation Notice
- 09/26/08: CIRB Initial Review Approval Letter (Protocol Version Date 09/04/08)
- 08/01/08: CIRB Initial Review Approval Letter (Protocol Version Date 07/10/08)
- 07/10/08: Group Response to Stipulations
- 06/12/08: CIRB Approval Pending Modification (Protocol Version Date 03/20/08)
- 07/21/08: Minutes - Group Response to Initial Review
- 05/19/08: Minutes - Initial Review
- 06/01/08: Journal of Clinical Oncology (Vol 26-Number 16)
- Specimen Banking Policies & Guide (Appendix C)
- Health Survey
- FACT/GOG Neurotoxicity Subscale

NCCTG-N0723

Initial Review (IR) 2008 Approval Protocol Version Date 07/14/08

Documents Posted:

- Protocol Version Date 07/14/08



- Protocol Version Date 06/11/08
- Protocol Version Date 03/13/08
- Informed Consent Document for Protocol Version Date 07/14/08
- CIRB Application (Protocol Version Date 07/14/08)
- CIRB Application (Protocol Version Date 06/11/08)
- 06/27/08: Primary Reviewer 1 Comments
- 06/27/08: Primary Reviewer 2 Comments
- 04/22/08: Pharmacist Comments
- 04/21/08: Primary Reviewer 1 Comments
- 04/21/08: Pharmacist Comments
- 10/23/08: CIRB Correction to Table of Initial Review (Protocol Version Date 03/13/08)
- 10/08/08: CIRB Acknowledgement of Receipt - Activation Notice & Notice of Study Amendment
- 10/01/08: NCCTG Activation - Correction Memo
- 07/18/08: CIRB Initial Review Approval Letter (Protocol Version Date 07/14/08)
- 07/11/08: CIRB Approval Pending Modification of Group Response
- 05/20/08: CIRB Table of Initial Review
- 06/27/08: Minutes - Group Response to Initial Review
- 04/21/08: Minutes - Initial Review

NSABP-B-43

Initial Review (IR) 2008 Approval Protocol Version Date 05/28/08
Documents Posted:

- Protocol Version Date 05/28/08
- Protocol Version Date 04/07/08
- Protocol Version Date 07/19/07
- Protocol Version Date 03/05/07
- Informed Consent Document for Protocol Version Date 05/28/08
- Informed Consent Document-Pre Entry-for Protocol Version Date 05/28/08
- Summary of CIRB Application Revisions (Protocol Version Date 05/28/08)
- CIRB Application (Protocol Version Date 05/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 04/07/08)
- CIRB Application (Protocol Version Date 04/07/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/19/07)
- CIRB Application (Protocol Version Date 07/19/07)
- CIRB Application (Protocol Version Date 03/05/07)
- 08/21/08: NSABP Response to CIRB
- 07/15/08: CIRB Initial Review Approval Letter (Protocol Version Date 05/28/08)
- 06/06/08: NSABP Response to CIRB
- 05/28/08: Change Memo (Protocol Version Date 05/28/08)



- 05/19/08: CIRB Approval Pending Modification (Protocol Version Date 04/07/08)
- 04/11/08: NSABP Response to CIRB
- 04/07/08: Change Memo (Protocol Version Date 04/07/08)
- 11/27/07: REVISED CIRB Approval Pending Modification Protocol (Version Date 07/19/07)
- 11/27/07: CIRB Approval Pending Modification (Protocol Version Date 07/19/07)
- 09/12/07: CIRB Approval Pending Modification (Protocol Version Date 07/19/07)
- 07/27/07: NSABP Response to CIRB
- 07/19/07: Change Memo (Protocol Version Date 07/19/07)
- 05/23/07: CIRB Approval Pending Modification (Protocol Version Date 03/05/07)
- 03/05/07: Change Memo (Protocol Version Date 03/05/07)
- 06/27/08: Minutes - Group Response - Initial Review
- 05/02/08: Minutes - Group Response - Initial Review
- 08/20/07: Minutes - Group Response - Initial Review
- 05/04/07: Minutes - Initial Review
- NSABP Guidelines for Breast Cancer Radiation Therapy (Version 2)
- NSABP Hope Poster

Other Activity Posted:

COG-AALL03B1

****Study Reactivation by COG - Effective October 17, 2008****

Amendment Review (AR): CIRB Acknowledgement of AALL03B1 Study
Reactivation

Documents Posted:

- 10/17/08: CIRB Acknowledgement of COG AALL03B1 Reactivation
- 10/17/08: Study Re-activation Memo

COG-AALL07P4

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/21/08)
- 10/23/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/21/08)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/21/08
- Informed Consent Document for Protocol Version Date 05/21/08



COG-AAML0523

Continuing Review (CR): Continuing Review August 2008

Documents Posted:

- 08/14/08: Primary Reviewer 1 Comments
- 08/14/08: Minutes - Continuing Review

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

COG-AAML06P1

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/26/07)
- 10/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/26/07)
- 10/03/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/26/07)
- 10/02/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/26/07)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/26/07
- Informed Consent Form for Protocol Version Date 02/26/07

COG-ACCL05C1

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/20/08)
- 10/21/08: CIRB Continuing Review Approval Letter (Protocol Version Date 02/20/08)
- 10/14/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/20/08)
- 10/02/08: CIRB Approval Pending Modification Letter (Protocol Version Date 02/20/08)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 02/20/08
- Informed Consent Document for Protocol Version Date 02/20/08

COG-ACNS0222

Continuing Review (CR): Continuing Review October 2008

Documents Posted:



- CIRB Continuing Review Application (Protocol Version Date 05/08/07)
- 10/24/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/08/07)
- 10/08/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/08/07)
- 10/02/08: CIRB Approval Pending Modification Letter (Protocol Version Date 05/08/07)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/08/07
- Informed Consent Document for Protocol Version Date 05/08/07
- 02/04/08: Study Progress Report
- 04/11/08: DSMC Report

COG-ADVL0221

Amendment Review (AR): Amendment #1 (Protocol Version Date 06/30/08) Study Reactivation at Dose Level #2

Documents Posted:

- 08/14/08: Primary Reviewer 1 Comments
- 08/14/08: Minutes - Amendment Review

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

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/30/08)
- 10/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/30/08)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/30/08
- Informed Consent Document for Protocol Version Date 06/30/08

COG-AEWS07P1

****Temporarily Closed to Accrual by COG - Effective October 9, 2008****

Amendment Review (AR): CIRB Acknowledgment of AEWS07P1 Temporary Closure to Accrual

Documents Posted:

- 10/17/08: CIRB Acknowledgment of Temporary Closure to Accrual Letter
- 10/17/08: Temporary Closure of Study AEWS07P1 Memo

COG-ALTE07C1

Initial Review 2008



Documents Posted:

- 08/14/08: Primary Reviewer 1 Comments
- 08/14/08: Primary Reviewer 2 Comments
- 08/14/08: Primary Reviewer 3 Comments
- 08/14/08: Minutes - Group Response to Initial Tabled Review

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

COG-ARAR0332

Continuing Review (CR): Continuing Review October 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/30/06)
- 10/21/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/30/08)
- 10/07/08: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/30/08)
- 10/02/08: CIRB Approval Pending Modification Letter (Protocol Version Date 08/30/06)
- 08/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/30/06
- Informed Consent Document for Protocol Version Date 08/30/06
- Informed Consent Document for Protocol Version Date 08/30/06 - Blood Sample
- Informed Consent Document for Protocol Version Date 08/30/06 - p53 Testing
- 02/04/08: Study Progress Report
- 04/11/08: DSMC Report

COG-AREN0533

Amendment Review (AR): Amendment #1 (Protocol Version Date 06/17/08)

Documents Posted:

- 08/14/08: Primary Reviewer 1 Comments
- 08/14/08: Minutes – Group Response to Amendment Review

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

COG-ARET0231

Amendment Review (AR): Amendment #2 (Protocol Version Date 06/26/08)

Documents Posted:



- 08/14/08: Primary Reviewer 1 Comments
- 08/14/08: Minutes - Amendment Review

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

Continuing Review (CR): Continuing Review October 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/26/08)
- 10/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/26/08)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 06/26/08
- Informed Consent Document for Protocol Version Date 06/26/08
- 02/04/08: Study Progress Report
- 04/11/08: DSMC Report

COG-ARET0321

Continuing Review (CR): Continuing Review October 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/08/07)
- 10/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/08/07)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/08/07
- Informed Consent Document for Protocol Version Date 08/08/07 - Stage 2 and 3
- Informed Consent Document for Protocol Version Date 08/08/07 - Stage 4a and 4b
- 08/25/08: Study Progress Report
- Fall Study Progress Report

COG-ASCT0431

Amendment Review (AR): Amendment #1B (Protocol Version Date 06/26/08)
Documents Posted:

- CIRB Application (Protocol Version Date 09/05/08)
- 10/03/08: CIRB Approval Amendment #1B (Protocol Version Date 09/05/08)
- 09/05/08: Change Memo (Protocol Version Date 09/05/08)
- Protocol Version Date 09/05/08
- Protocol Version Date 09/05/08 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 09/05/08



Continuing Review (CR): Continuing Review October 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/23/07)
- 10/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 09/05/08)
- 09/08/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 09/05/08
- Informed Consent Document for Protocol Version Date 09/05/08
- 04/11/08: DSMC Report

ECOG-E1A06

Amendment Review (AR): Addendum #1 (Protocol Version Date 09/24/08)
Documents Posted:

- 06/09/08: Change Memo
- CIRB Application (Protocol Version Date 06/09/08)
- Summary of CIRB Application Revisions (Protocol Version Date 06/09/08)
- 10/06/08: CIRB Addendum 1 Approval Letter (Protocol Version Date 09/24/08)
- 09/24/08: ECOG Cover Memo
- 08/14/08: CIRB Approval Pending Modification (Protocol Version Date 06/09/08)
- Protocol Version Date 09/24/08 [Per Add1]
- Protocol Version Date 06/09/08
- Informed Consent Document for Protocol Version Date 09/24/08 [Per Add1]
- 07/21/08: Primary Reviewer 1 Comments
- 07/21/08: Minutes - Addendum 1 Review

ECOG-E2805

Amendment Review (AR): Update #3 (Protocol Version Date 09/30/08)
Documents Posted:

- 09/30/08: Change Memo (Protocol Version Date 09/30/08)
- CIRB Application (Protocol Version Date 09/30/08)
- Summary of CIRB Application Revisions (Protocol Version Date 09/30/08)
- 10/21/08: CIRB Update 3 Approval Letter (Protocol Version Date 09/30/08)
- Protocol Version Date 09/30/08 [Per Up3]
- Informed Consent Document for Protocol Version Date 09/30/08 [Per Up3]

ECOG-E3805

Amendment Review (AR): Update #4 (Protocol Version Date 10/01/08)
Documents Posted:



- 10/01/08: Change Memo (Protocol Version Date 10/01/08)
- CIRB Application (Protocol Version Date 10/01/08)
- Summary of CIRB Application Revisions (Protocol Version Date 10/01/08)
- 10/21/08: CIRB Update 4 Approval Letter (Protocol Version Date 10/01/08)
- Protocol Version Date 10/01/08 [Per Up4]
- Informed Consent Document for Protocol Version Date 10/01/08 [Per Up4]

NCCTG-N0147

****Effective October 24, 2008 at 8:00 AM CDT accrual of patients 70 years of age and older is temporarily suspended.****

Documents Posted:

- 10/24/08: NCCTG Notice of Accrual Status Change
- 10/24/08: CIRB Acknowledgement of Temporary Closure of Accrual-Patients Age 70 or greater
- 10/24/08: Notice of Accrual Suspension-Physician Letter
- 10/24/08: Notice of Accrual Suspension-Participant Letter

NSABP-R-04

Amendment Review (AR) Amendment 4 Approval Protocol Version Date 05/28/08

Documents Posted:

- 05/28/08: Change Memo (Protocol Version Date 05/28/08)
- CIRB Application (Protocol Version Date 05/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 05/28/08)
- 06/27/08: CIRB Amendment 4 Approval Letter (Protocol Version Date 05/28/08)
- Protocol Version Date 05/28/08 [Per Am4]
- Informed Consent Document for Protocol Version Date 05/28/08 [Per Am4]
- Informed Consent Document (Tissue) for Protocol Version Date 05/28/08 [Per Am4]
- 06/27/08: Primary Reviewer 1 Comments
- 06/27/08: Minutes - Amendment 4 Review

NSABP-R-04

Amendment Review (AR) Amendment 5 Approval Protocol Version Date 09/04/08

Documents Posted:

- 09/04/08: Change Memo (Protocol Version Date 09/04/08)
- CIRB Application (Protocol Version Date 09/04/08)
- Summary of CIRB Application Revisions (Protocol Version Date 09/04/08)
- 10/06/08: CIRB Amendment 5 Approval Letter (Protocol Version Date 09/04/08)
- Protocol Version Date 09/04/08 [Per Am5]
- Informed Consent Document for Protocol Version Date 09/04/08 [Per Am5]
- Informed Consent Document (Tissue) for Protocol Version Date 09/04/08 [Per Am5]



RTOG-0320

Amendment Review (AR) Amendment 5 Approval Protocol Version Date 07/22/08

Documents Posted:

- 07/22/08: Change Memo (Protocol Version Date 07/22/08)
- CIRB Application (Protocol Version Date 07/22/08)
- Summary of CIRB Application Revisions (Protocol Version Date 07/22/08)
- 09/17/08: CIRB Amendment 5 Approval Letter (Protocol Version Date 07/22/08)
- Protocol Version Date 07/22/08 [Per Am5]
- Protocol Version Date 07/22/08 (Highlighted) [Per Am5]
- Informed Consent Document for Protocol Version Date 07/22/08 [Per Am5]

RTOG-0522

Amendment Review (AR) Amendment 4 Approval October 2008 Protocol Version Date 08/25/08

Documents Posted:

- 08/25/08: Change Memo (Protocol Version Date 08/25/08)
- CIRB Application (Protocol Version Date 08/25/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/25/08)
- 10/06/08: CIRB Amendment 4 Approval Letter (Protocol Version Date 08/25/08)
- Protocol Version Date 08/25/08
- Protocol Version Date 08/25/08 (Highlighted)
- Informed Consent Document for Protocol Version Date 08/25/08 [Per Am4]
- 10/03/08: Primary Reviewer 1 Comments

RTOG-0522

Continuing Review (CR) Approval October 2008 Protocol Version Date 08/25/08

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/25/08)
- 10/27/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/25/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 08/25/08
- Informed Consent Document for Protocol Version Date 08/25/08 [Per CR 08]
- 10/20/08: Primary Reviewer 1 Comments
- 06/19/08: DMC Minutes
- June 2008 - Study Summary

RTOG-0617

Amendment Review (AR) Amendment 2 Approval Protocol Version Date 08/29/08

Documents Posted:

- 08/29/08: Change Memo (Protocol Version Date 08/29/08)



- CIRB Application (Protocol Version Date 08/29/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/29/08)
- 09/17/08: CIRB Amendment 2 Approval Letter (Protocol Version Date 08/29/08)
- Protocol Version Date 08/29/08 [Per Am2]
- Protocol Version Date 08/29/08 [Per Am2] Highlighted
- Informed Consent Document for Protocol Version Date 08/29/08 [Per Am2]

SWOG-S0226

Continuing Review (CR) Approval October 2008 Protocol Version Date 08/11/08
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/11/08)
- 10/27/08: CIRB Continuing Review Approval Letter (Protocol Version Date 08/11/08)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 08/11/08
- Informed Consent Document for Protocol Version date 08/11/08 [Per CR Oct 08]
- 10/20/08: Primary Reviewer 1 Comments
- 05/09/08 DSMC Minutes
- Fall 2008 - Study Summary

SWOG-S0500

Continuing Review (CR) Approval October 2008 Protocol Version Date 05/15/07
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/15/07)
- 10/27/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/15/07)
- 09/05/08: Continuing Review Reminder Notice
- Protocol Version Date 05/15/07
- Informed Consent Document for Protocol Version Date 05/15/07 [CR08]
- 10/20/08: Primary Reviewer 1 Comments
- 05/09/08: DSMC Minutes
- Fall 2008 - Study Summary

SWOG-S0777

Amendment Review (AR) Revision 1 Approval Protocol Version Date 09/17/08
Documents Posted:

- Change Memo (Protocol Version Date 09/17/08)
- CIRB Application (Protocol Version Date 09/17/08)
- Summary of CIRB Application Revisions (Protocol Version Date 09/17/08)
- CIRB Application (Protocol Version Date 07/22/08)



- Summary of CIRB Application Revisions (Protocol Version Date 07/22/08)
- 09/26/08: CIRB Revision 1 Approval Letter (Protocol Version Date 09/17/08)
- 09/15/08: CIRB Approval Pending Modification-Revision 1 (Protocol Version Date 07/22/08)
- 09/09/08: CIRB Acknowledgement of Receipt-Revision 1 Correction Memo
- 08/27/08: SWOG Correction Memo
- Protocol Version Date 09/17/08
- Protocol Version Date 07/22/08
- Informed Consent Document for Protocol Version Date 09/17/08 [Per Rev1]
- 08/18/08: Primary Reviewer 1 Comments
- 08/18/08: Minutes - Revision 1 Review

Serious Adverse Events

Study: COG AEWS 0521

SAE Posted: 1199283 FU1, 1536472 FU1, 254163 FU2, 1230483 FU1

Study: COG ADVL 0525

SAE Posted: DE200802002043 FU3, DE200802002043 FU2, BE200803004329 FU1, US200712004401 FU1, DE200802000020, US200804006797

Study: COG ADVL 0221

SAE Posted: IE-JNJFOC-20080302875, US-JNJFOC-20080206633, US-JNJFOC-20080400179 FU2, US-JNJFOC-20061203739 FU3, US-JNJFOC-20071007918 FU4, US-JNJFOC-20070902657 FU3, US-JNJFOC-20070902093 FU2, US-JNJFOC-20080100956 FU2, GB-JNJFOC-20071109894 FU4

Corrections to Previous Study Activity Updates

CALGB-SWOG-C80405

Amendment Review (AR) Update 5 Approval (Protocol Version Date 08/27/08)

Documents Posted:

10/21/08: CORRECTED CIRB Amendment 5 Approval Letter (08/27/08)

Correction:

This letter is to replace the previous correction letter dated September 19, 2008 to correct the protocol version date from 08/29/2007 to 08/27/2008.

NCIC CTG-MA.27

Documents Posted:

10/28/08: CIRB Acknowledgement of Permanent Closure to New Accrual

Correction:



Language was changed on 10/28/08 for clarification that closure was to new accrual not to study treatment.

NSABP-R-04

Amendment Review (AR) Amendment 4 Approval (Protocol Version Date 05/28/08)

Documents Posted:

Informed Consent Document (Tissue) for Protocol Version Date 05/28/08 (Am4)

Informed Consent Document for Protocol Version Date 05/28/08 (Am4)

Correction:

Consent pagination error corrected.

SWOG-S0307

Amendment Review (AR) Revision 4 Approval (Protocol Version Date 07/25/08)

Documents Posted:

Informed Consent Document for Protocol Version Date 07/25/08 [Rev4]

Informed Consent Document for Protocol Version Date 07/25/08 (Local Instructions) [Rev4]

Correction:

Local Notes/Instructions split from Informed Consent Document into separate document.

SWOG-S0421

Amendment Review (AR) Revision 2 Approval (Protocol Version Date 06/11/08)

Documents Posted:

Informed Consent Document for Protocol Version Date 06/11/08 [Rev2]

Informed Consent Document for Protocol Version Date 06/11/08 (Local Notes) [Rev2]

Continuing Review (CR) Approval September 2008 (Protocol Version Date 06/11/08)

Documents Posted:

Informed Consent Document for Protocol Version Date 06/11/08 [Sep08CR]

Informed Consent Document for Protocol Version Date 06/11/08 (Local Notes) [Per Sep 08 CR]

Correction:

Local Notes/Instructions split from Informed Consent Document into separate document.

SWOG-9007

Amendment Review (AR) Revision 35 Approval (Protocol Version Date 06/23/08)



Documents Posted:

10/21/08: CORRECTED CIRB Revision 35 Approval Letter (Protocol Version Date 06/23/08)

Correction:

This letter is to replace the previous letter dated August 7, 2008 in order to correct the CIRB approval expiration date.

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

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