



NCI Central IRB Study Activity Update

May 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. ******



Other Activity Posted:

CALGB-SWOG-C80405

Amendment Review (AR): **Cetuximab Recall**

Documents Posted:

- 04/15/09: CIRB Acknowledgement of Cetuximab Recall Memo
- 03/09/09: Cetuximab Recall Memo

CALGB-40302

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 04/02/08)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/02/08)
- 03/04/09: Continuing Review Reminder Notice
- Protocol Version Date 04/02/08
- Informed Consent Document for Protocol Version Date 04/02/08 [CR09]
- 05/07/09: Primary Reviewer 1 Comments
- 11/14/08: DSMB Report
- November 2008 - Study Summary

CALGB-90206

Continuing Review (CR): Approval April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/15/07)
- 05/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/15/07)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 08/15/07
- Informed Consent Document for Protocol Version Date 08/15/07
- 04/20/09: Primary Reviewer 1 Comments
- 11/14/08: DSMB Report
- November 2008 - Study Summary
- Journal of Clinical Oncology (Rini) Abstract



COG-AALL03N1

Continuing Review (CR): Approval April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/03/07)
- 05/07/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/03/07)
- 04/20/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 01/03/07)
- 04/09/09: CIRB Approval Pending Modification Letter (Protocol Version Date 01/03/07)
- 03/05/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/03/07
- Informed Consent Document for Protocol Version Date 01/03/07
- 04/02/09: Primary Reviewer 1 Comments
- 08/25/08: Study Progress Report

COG-AALL0331

Amendment Review (AR): Amendment #4 (Protocol Version Date 03/25/09)

Documents Posted:

- CIRB Application (Protocol Version Date 03/25/09)
- 05/11/09: COG AALL0331 Amendment #4 Activation Memo
- 05/05/09: CIRB Approval of COG AALL0331 Amendment #4 (Protocol Version Date 03/25/09)
- 03/25/09: COG Change Memo (Protocol Version Date 03/25/09)
- Protocol Version Date 03/25/09
- Protocol Version Date 03/25/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 03/25/09: Part I - Induction Therapy
- Informed Consent Document for Protocol Version Date 03/25/09: Standard Risk - Low
- Informed Consent Document for Protocol Version Date 03/25/09: Standard Risk - Average
- Informed Consent Document for Protocol Version Date 03/25/09: Standard Risk - High
- Informed Consent Document for Protocol Version Date 03/25/09: Treatment Changes



COG-AALL0433

Continuing Review (CR): Approval March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 11/12/08)
- 05/07/09: CIRB Continuing Review Approval Letter (Protocol Version Date 11/12/08)
- 04/17/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 11/12/08)
- 03/31/09: CIRB Approval Pending Modification Letter (Protocol Version Date 11/12/08)
- 02/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 11/12/08
- Informed Consent Document for Protocol Version Date 11/12/08
- 05/07/09: Primary Reviewer 1 Comments
- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review
- Spring 2009 Study Progress Report
- 10/02/08: DSMC Report

COG-AALL0434

Continuing Review (CR): Approval March 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 10/31/08)
- 05/07/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/31/08)
- 04/17/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 10/31/08)
- 03/31/09: CIRB Approval Pending Modification Letter (Protocol Version Date 10/31/08)
- 02/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 10/31/08
- Informed Consent Document for Protocol Version Date 10/31/08: Part I - Induction Therapy
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - Low Risk
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - Intermediate Risk
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - High Risk
- Informed Consent Document for Protocol Version Date 10/31/08: Part II - Induction Failure
- 05/07/09: Primary Reviewer 1 Comments



- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review
- 10/02/08: DSMC Report
- 08/25/08: Study Progress Report

COG-AALL07P4

Amendment Review (AR): Amendment #1 (Protocol Version Date 04/02/09)
Documents Posted:

- CIRB Application (Protocol Version Date 04/02/09)
- CIRB Application (Protocol Version Date 02/27/09)
- 05/11/09: COG AALL07P4 Amendment #1 Activation Memo
- 04/23/09: CIRB Approval of COG AALL07P4 Amendment #1 (Protocol Version Date 04/02/09)
- 04/02/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 02/27/09)
- 04/02/09: CIRB Approval Pending Modification Letter (Protocol Version Date 02/27/09)
- 02/27/09: COG Change Memo (Protocol Version Date 02/27/09)
- Protocol Version Date 04/02/09
- Protocol Version Date 04/02/09 - Highlighted Changes
- Protocol Version Date 02/27/09
- Protocol Version Date 02/27/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 04/02/09

COG-ACNS0334

Continuing Review (CR): Approval March 2009
Documents Posted:

- 04/21/09: Primary Reviewer 1 Comments

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

COG-ADVL06B1

****Stratum 5 and Stratum 7 Closed to Accrual by COG - Effective May 8, 2009****

Amendment Review (AR): **Acknowledgement of COG ADVL06B1 Stratum 5 and Stratum 7 Closure to Enrollment (05/08/2009)**

Documents Posted:

- 05/11/09: CIRB Acknowledgement - ADVL06B1 Stratum 5 and Stratum 7 Closures
- 05/08/09: COG Notice - ADVL06B1 Stratum 5 and Stratum 7 Closures



COG-ADVL0821

Amendment Review (AR): Amendment #1 (Protocol Version Date 03/26/09)
Documents Posted:

- CIRB Application (Protocol Version Date 03/26/09)
- 05/08/09: CIRB Acknowledgement of IMC-A12 Action Letter
- 05/08/09: COG Action Letter Notice
- 03/26/09: COG Change Memo (Protocol Version Date 03/26/09)
- 03/30/09: CIRB Amendment 1 Approval Letter (Protocol Version Date 03/26/09)
- OHRP: IRB Review of Protocol and Informed Consent Changes
- Protocol Version Date 03/26/09
- Protocol Version Date 03/26/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 03/26/09

COG-AGCT0521

Continuing Review (CR): Approval April 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/28/07)
- 05/08/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/28/07)
- 04/20/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/28/07)
- 04/09/09: CIRB Approval Pending Modification Letter (Protocol Version Date 08/28/07)
- 03/05/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/28/07
- Informed Consent Document for Protocol Version Date 08/28/07
- 04/02/09: Primary Reviewer 1 Comments
- Spring 2009 Study Progress Report
- 10/07/08: DSMC Report
- 08/25/08: Study Progress Report

COG-AHOD0431

Continuing Review (CR): Approval March 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/11/07)
- 04/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/11/09)
- 04/27/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/11/07)
- 04/24/09: COG Memo re Benzyl Alcohol Concentrations Clarification



- 04/21/09: CIRB Approval Pending Modification Letter (Protocol Version Date 05/11/07)
- 04/13/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 05/11/07)
- 03/31/09: CIRB Approval Pending Modification Letter (Protocol Version Date 05/11/07)
- 02/06/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 05/11/07
- Informed Consent Document for Protocol Version 05/11/07 - Initial Treatment
- Informed Consent Document for Protocol Version 05/11/07 - Relapse Treatment
- 03/12/09: Primary Reviewer 1 Comments
- 03/12/09: Minutes - Continuing Review
- Spring 2009 Study Progress Report
- 11/05/08: DSMC Report

COG-ALTE05N1

Amendment Review (AR): Amendment #1A (Protocol Version Date 04/15/09)
Documents Posted:

- CIRB Application (Protocol Version Date 04/15/09)
- 05/11/09: COG ALTE05N1 Amendment #1 Activation Memo
- 05/05/09: CIRB Approval of COG ALTE05N1 Amendment #1 (Protocol Version Date 04/15/09)
- 04/15/09: COG Change Memo (Protocol Version Date 04/15/09)
- Protocol Version Date 04/15/09
- Protocol Version Date 04/15/09 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 09/10/09

COG-ANBL00P3

Continuing Review (CR): Approval April 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/31/07)
- 05/06/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/31/07)
- 04/10/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 01/31/07)
- 04/09/09: CIRB Approval Pending Modification Letter (Protocol Version Date 01/31/07)
- 03/05/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 01/31/07
- Informed Consent Document for Protocol Version Date 01/31/07 - Low Risk



- Informed Consent Document for Protocol Version Date 01/31/07 - Intermediate/High Risk
- 04/02/09: Primary Reviewer 1 Comments
- 11/05/08: DSMC Report
- 08/25/08: Study Progress Report

COG-ANBL0332

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 03/28/07)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/28/07)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 03/28/07
- Informed Consent Document for Protocol Version Date 03/28/07

COG-AOST06B1

Continuing Review (CR): Approval April 2009

Documents Posted:

- 04/02/09: Primary Reviewer 1 Comments

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

COG-ARAR0331

Amendment Review (AR): Amendment #1 (Protocol Version Date 04/14/09)

Documents Posted:

- CIRB Application (Protocol Version Date 04/14/09)
- CIRB Application (Protocol Version Date 01/14/09)
- 05/11/09: COG ARAR0331 Amendment #1 Activation Memo
- 04/14/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 04/14/09)
- 04/14/09: COG Change Memo (Protocol Version Date 04/14/09)
- 04/05/09: CIRB Approval of COG AALL0331 Amendment #1 (Protocol Version Date 04/14/09)
- 02/27/09: CIRB Approval Pending Modification Letter (Protocol Version Date 01/14/09)
- 01/14/09: COG Change Memo (Protocol Version Date 01/14/09)
- Protocol Version Date 04/14/09
- Protocol Version Date 04/14/09 - Highlighted Changes
- Protocol Version Date 01/14/09
- Protocol Version Date 01/14/09 - Highlighted Changes



- Informed Consent Document for Protocol Version Date 04/14/09
- 02/12/09: Primary Reviewer 1 Comments
- 02/12/09: Minutes - Amendment Review

COG-AREN0321

Continuing Review (CR): Approval March 2009
Documents Posted:

- 04/30/09: CIRB Approval / Disapproval of the Continuing Review of COG AREN0321 Letter (Protocol Version Date 11/20/06)
- 04/30/09: Correction Letter for the AREN0321 Continuing Review 2009 Approval Letter

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

COG-ARET0331

****Study Reactivation by COG - Effective May 4, 2009****

Amendment Review (AR): **CIRB Acknowledgement of COG ARET0331 Re-activation (Protocol Version Date 09/14/07)**

Documents Posted:

- 05/11/09: CIRB Acknowledgement - Reactivation of ARET0331
- 05/04/09: COG Notice - Re-activation of ARET0331

COG-ARST0332

Continuing Review (CR): Approval April 2009
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/22/06)
- 05/07/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/22/06)
- 04/17/09: COG Response to Approval Pending Modification Letter (Protocol Version Date 08/22/06)
- 04/09/09: CIRB Approval Pending Modification Letter (Protocol Version Date 08/22/06)
- 03/05/09: CIRB Continuing Review Reminder Notice
- Protocol Version Date 08/22/06
- Informed Consent Document for Protocol Version Date 08/22/06
- 04/02/09: Primary Reviewer 1 Comments
- 10/07/08: DSMC Report
- 08/25/08: Study Progress Report



ECOG-E1Y03

Continuing Review (CR): Approval April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 08/13/08)
- 04/30/09: CIRB Continuing Review Approval Letter (Protocol Version Date 08/13/08)
- 03/06/09: Continuing Review Reminder Notice
- Protocol Version Date 08/13/08
- Informed Consent Document for Protocol Version Date 08/13/08)

ECOG-E1305

Amendment Review (AR): Update #3 (Protocol Version Date 04/29/09)

Documents Posted:

- 04/29/09: ECOG Change Memo (Protocol Version Date 04/29/09)
- CIRB Application (Protocol Version Date 04/29/09)
- Summary CIRB Application Revisions (Protocol Version Date 04/29/09)
- 05/13/09: CIRB Update 3 Approval Letter (Protocol Version Date 04/29/09)
- Protocol Version Date 04/29/09
- Informed Consent Document for Protocol Version Date 04/29/09 [up3]

ECOG-E1899

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/16/04)
- 05/11/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/16/04)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 06/16/04
- Informed Consent Document for Protocol Version Date 06/16/04
- 05/07/09: Primary Reviewer 1 Comments
- June 2005 - Study Summary
- 11/02/04: DMC Report

ECOG-E2905

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/29/09)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/29/09)



- 03/06/09: Continuing Review Reminder Notice
- Protocol Version Date 01/29/09
- Informed Consent Document for Protocol Version 01/29/09 [CR09]
- 05/07/09: Primary Reviewer 1 Comments
- November 2008 - Study Summary

ECOG-E3805

Amendment Review (AR): Update #5 (Protocol Version Date 04/23/09)

Documents Posted:

- 04/23/09: Change Memo (Protocol Version Date 04/23/09)
- CIRB Application (Protocol Version Date 04/23/09)
- Summary of CIRB Application Revisions (Protocol Version Date 04/23/09)
- 04/30/09: CIRB Update 5 Approval Letter (Protocol Version Date 04/23/09)
- Protocol Version Date 04/23/09
- Informed Consent Document for Protocol Version Date 04/23/09 [Per Up5]

ECOG-E3999

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/01/05)
- 05/07/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/01/05)
- 02/04/09: Continuing Review Reminder Notice
- Protocol Version Date 06/01/05
- Informed Consent Document for Protocol Version Date 06/01/05
- 05/07/09: Primary Reviewer 1 Comments
- June 2006 - Study Summary
- 04/18/06: DMC Recommendations

ECOG-E4599

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 01/19/07)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/19/07)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 01/19/07
- Informed Consent Document for Protocol Version Date 01/19/07
- 05/07/09: Primary Reviewer 1 Comments
- 03/20/09: Journal of Clinical Oncology (Sandler)
- 12/14/06: New England Journal of Medicine (Sandler)



- June 2006 - Study Summary
- March-April 2005 DMC Report

ECOG-E5202

Amendment Review (AR): **Suspension of Accrual - Effective April 29, 2009**

Documents Posted:

- 04/30/09: CIRB Acknowledgement of ECOG Notification of Suspension to Accrual
- 04/29/09: ECOG Notification of Suspension of Accrual

ECOG-E5204

Amendment Review (AR): **Closure to Accrual - Effective April 29, 2009**

Documents Posted:

- 04/30/09: CIRB Acknowledgement of ECOG Closure to Accrual Notice
- 04/29/09: ECOG Closure to Accrual Notice
- Informed Consent Document for Protocol Version Date 01/21/09

GOG-0219

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 02/24/09)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/24/09)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 02/24/09
- Informed Consent Document for Protocol Version Date 02/24/09 [CR09]
- 05/07/09: Primary Reviewer 1 Comments
- January 2009 - Study Summary
- 07/19/08: DSMB

GOG-0240

Amendment Review (AR): Administrative Update #1 (Protocol Version Date 03/10/09)

Documents Posted:

- 04/20/09: Change Memo for Administrative Update of 04/20/09 (Protocol Version Date 03/10/09)
- 05/12/09: CIRB Administrative Update #1 Approval Letter (Protocol Version Date 03/10/09 Update Date 04/20/09)
- Protocol Version Date 03/10/09 [04/20/09 Update]
- APPENDIX IV: Smoking History Questionnaire (04/20/09 Update)
- Informed Consent Document for Protocol Version Date 03/10/09



NCCTG-N06C6

Continuing Review (CR): Approval April 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/19/08)
- 05/05/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/19/08)
- 02/05/09: Continuing Review Reminder Notice
- Protocol Version Date 05/19/08
- Informed Consent Document for Protocol Version Date 05/19/08 [Per Apr09 CR]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 05/19/08
- 04/20/09: Primary Reviewer 1 Comments
- 10/21/08: DMC AE Report

NCCTG-N0723

Amendment Review (AR): Addendum #2 (Protocol Version Date 02/25/09)

Documents Posted:

- Change Memo (Protocol Version Date 02/25/09)
- CIRB Application (Protocol Version Date 02/25/09)
- Summary of CIRB Application Revisions (Protocol Version Date 02/25/09)
- 4/13/09: CIRB Approval Letter Addendum 2 (Protocol Version Date 02/25/09)
- Protocol Version Date 02/25/09
- Informed Consent Document for Protocol Version Date 02/25/09 [ad2]
- Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 02/25/09 [ad2]
- 04/03/09: Primary Reviewer 1 Comments
- 04/03/09: Primary Reviewer 2 Comments

NSABP-C-08

Amendment Review (AR): [Press Release - April 21, 2009](#)

Documents Posted:

- 05/01/09: Acknowledgement of NSABP C-08 News Release (April 21, 2009)
- 04/21/09: NSABP C-08 News Release



RTOG-0415

Continuing Review (CR): Approval May 2009

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/03/07)
- 05/12/09: CIRB Continuing Review Approval Letter (Protocol Version Date 12/03/07)
- 03/05/09: Continuing Review Reminder Notice
- Protocol Version Date 12/03/07
- Informed Consent Document for Protocol Version Date 12/03/07 [CR09]
- Informed Consent Document -Tissue Protocol Version Date 12/03/07 [CR09]
- 05/07/09: Primary Reviewer 1 Comments
- 01/09/09: DMC Minutes
- January 2009 - Study Summary

RTOG-0436

Amendment Review (AR): [Cetuximab Recall](#)

Documents Posted:

- 04/15/09: CIRB Acknowledgement of Cetuximab Recall Memo
- 03/09/09: Cetuximab Recall Memo

RTOG-0522

Amendment Review (AR): [Cetuximab Recall](#)

Documents Posted:

- 04/15/09: CIRB Acknowledgement of Cetuximab Recall Memo
- 03/09/09: Cetuximab Recall Memo

RTOG-0617

Amendment Review (AR): [Cetuximab Recall](#)

Documents Posted:

- 04/15/09: CIRB Acknowledgement of Cetuximab Recall Memo
- 03/09/09: Cetuximab Recall Memo

SWOG-S0307

Amendment Review (AR): Temporary Shortage of Clodronate Tablets

Documents Posted:

- 04/15/09: CIRB Acknowledgement of Clodronate Shortage Memo
- 03/15/09: Shortage of Clodronate Tablets Memo



Serious Adverse Events

Study: N/A

SAE Posted:

Corrections to Previous Study Activity Updates

GOG-0249

Initial Review 2009 Approval
Documents Posted:

05/05/09: CIRB Final Approval of GOG 0249-correction

05/05/09: Correction to CIRB Final Approval Dated November 7, 2008

Correction:

The **GOG 0249 Group Response to Initial Review** approval letter dated **November 7, 2008** contains an error. The original letter stated the study was approved on October 3, 2008 but this was the date it was approved pending modifications. The letter should **have stated that the study was given final approval on October 30, 2008.**

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.