National Cancer Institute
Central IRB Initiative

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MEMORANDUM

From: John Horigan, MA, CIP
CIRB Administrator

Date: October 28, 2010

Subject: **Clarification of Local IRB Responsibilities Regarding Review of Adverse Events**

The CIRB's memorandum, "Review of Adverse Events for Phase 3 Clinical Trials," dated April 1, 2010, described a change in process for the CIRB's review of adverse event reports distributed by the Cooperative Groups for Phase 3 Clinical Trials. This change in process does not shift responsibility for review of these reports to the local IRB.

The CIRB is still responsible for review of individual adverse event reports distributed by the Cooperative Groups. The CIRB fulfills this responsibility by complying with the recommendations contained in the Federal Guidances. As noted in the April 1, 2010 memorandum, since the Federal Guidances recommend that sponsors can better assess individual adverse event reports than IRBs, the CIRB's SOPs were changed to reflect the Guidances.

In summary, when an IRB accepts facilitated review for a study, individual adverse event reports distributed by the Cooperative Group for that study need not be submitted to the local IRB. Per the Authorization Agreement's "Division of Responsibilities between the Central IRB and Enrolled Local Institutions" document, the CIRB is responsible for review of these reports.