

Memo To: CPCRA 065 Investigators of Record

From: Rebecca DerSimonian, Sc.D., Mathematical Statistician
Biostatistics Research Branch, DAIDS

Subject: Report of DSMB Review

Date: November 12, 2004

I am providing the following information concerning the status of CPCRA 065 (**SMART**) "A Large, Simple Trial Comparing Two Strategies for Management of Anti-Retroviral Therapy" which you should forward to your Institutional Review Board in fulfillment of the NIH Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials (release date: June 11, 1999).

CPCRA 065 is a multi-site clinical trial supported by the National Institute of Allergy and Infectious Diseases, NIH, through the Terry Bein Community Programs for Clinical Research on AIDS (CPCRA). NIAID has established a Data and Safety Monitoring Board (DSMB) consisting of physicians, laboratory scientists, statisticians and ethicists, independent of the study investigators, to periodically review the emerging outcome and safety data from this trial.

The DSMB met on November 3, 2004, in Bethesda, Maryland. After carefully reviewing comparative safety and efficacy data from all participating sites, the Board concluded that there are no concerns arising from either efficacy or safety data at the present time warranting a change in the conduct of CPCRA 065. The next full DSMB review is expected to take place in approximately one year.

Questions about the DSMB review may be directed to me at 301-435-7181.