



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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Public Health Service  
National Institutes of Health  
[www.nih.gov](http://www.nih.gov)  
Building: Rockledge

**Attention:** Investigators/Study Coordinators

**Re:** ESPRIT 001 Report of DSMB Review, dated November 15, 2006

**Note:** This report is from a DAIDS-sponsored study.

Dear Investigator/Study Coordinator:

Attached please find important information regarding a recent DSMB review and summary.

You are required to forward this summary report to your Institutional Review Board (IRB). The DSMB summary report is an additional document to submit to your IRB. This does not replace the other Safety Memos and Safety Reports you have received or may receive in the future. The safety reporting process for DAIDS-sponsored trials remains in place with no changes.

If you have any questions regarding the DSMB summary, please contact Dr. Rebecca DerSimonian Sc.D., Mathematical Statistician, at (301) 435-7181.

Sincerely,

**Lawrence Allan**

Regulatory Affairs Specialist

RAB/DAIDS/NIAID

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Memo To:        ESPRIT Investigators of Record

From:            Rebecca DerSimonian, Sc.D., Mathematical Statistician  
                    Biostatistics Research Branch, Division of Clinical Research

Subject:         Report of DSMB Review

Date:             November 15, 2006

I am providing the following information concerning the status of ESPRIT "A Randomized, Open Label, Phase III, International Study of Subcutaneous Recombinant IL-2 (Proleukin®) in Patients with HIV-1 Infection and CD4<sup>+</sup> Cell Counts  $\geq 300/\text{mm}^3$ : Evaluation of Subcutaneous Proleukin® in a Randomized International Trial (ESPRIT)" 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).

ESPRIT is a multinational clinical trial supported by the National Institute of Allergy and Infectious Diseases, NIH. 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. To reflect the multinational nature of this trial, the Board for ESPRIT includes several international scientists.

The DSMB met face-to-face on November 6, 2006 in Bethesda, MD. 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 ESPRIT. The next full DSMB data review is expected to take place in one year.

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