

MOUNT SINAL SCHOOL OF MEDICINE Institutional Review Board

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Date: September 2, 2004

GCO Project # 04-0469 0001 01 PE * Principal Investigator Maria New, M.D.

NIH

Dear Sir/Madam,

The project entitled ANDROGEN METABOLISM IN CHILDHOOD includes activities involving human subjects. This project, which includes 3 subprojects, was reviewed at convened meetings of the Institutional Review Board of the Mount Sinai School of Medicine or 8/3/2004 and 8/17/04 in accordance with our assurance to the Department of Health and Human Services FWA # 00005656. The subprojects "PROJECT #1 HYPO-HYPERADRENAL STATES" and "PROJECT #3 PRENATAL DIAGNOSIS AND TREATMENT" received final IRB approval on 9/2/2004. The subproject "PROJECT #2 LOW-RENIN HYPERTENSION" has not yet received final approval pending resolution of an investigation into the GMP status of the injectable cortisol.

Sincerely yours,

Jeffrey H. Silverstein, M.D.

Chairpersor

Institutional Review Board