DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 20, 2005

Robert S. Chang, Ph.D.
Vice President for Research
University of South Florida
4202 E. Fowler Avenue, ADM 200
Tampa, FL 33620-5920

Gary A. Carnes
President and Chief Executive Officer
All Children's Health System, Inc.
801 Sixth Street South
St. Petersburg, FL 33701

RE: Human Research Subject Protections Under Federalwide Assurances FWA-1669 and FWA-997

Research Activity: **Very High Dose Recombinant Erythropoietin (rEpo) as a Neuroprotectant for Neonates at Risk for Periventricular-Intraventricular Hemorrhage (PV-IVH)**
Investigators: **Stacey M. Levitt, Darlene A. Calhoun, Bruce Martin, Samuel E. Fox, and Robert D. Christensen**

Dear Dr. Chang and Mr. Carnes:

The Office for Human Research Protections (OHRP) has reviewed the University of South Florida's (USF) and All Children's Health System, Inc.'s (ACH) October 6, 2005 report in response to OHRP's August 26, 2005 letter regarding the above-referenced research.

In its August 26, 2005 letter, OHRP made the following finding of noncompliance:

> The ACH IRB lacked sufficient information to make the determinations required for approval of the above-referenced research under HHS regulations at 45 CFR 46.111.

Corrective Actions: OHRP acknowledges that the ACH institutional review board (IRB) continues to evaluate and improve its review process. The ACH IRB has improved its reviewer checklist to include references and outlines to help ensure that appropriate regulatory issues are addressed during the review process. In addition, the ACH IRB minutes include greater detailed discussion and documentation of decisions made by the IRB. The ACH IRB is revising its research application to require submission of additional drug information to allow for a better assessment of risks associated with protocols. The ACH has obtained an educational support grant to establish a structured education program for IRB members, research investigators, and others involved in human subject research activities. OHRP finds that these corrective actions adequately address the above finding. As a result of this determination, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institutions to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Barry Bercu, IRB Chair, USF
Dr. Paul Stiles, IRB Chair, USF
Ms. Norma Epley, Assistant Director, Research Compliance, USF
Ms. Holly L. Pageau, Administrative Research Coordinator, ACH
Dr. Atilano Lacson, IRB Chair, ACH
Dr. Lana Skirboll, NIH
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Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP