[January 12, 2007]

Mary Ellen Sheridan, Ph.D.
Associate Vice President for Research
University Research Administration
The University of Chicago
970 East 58th Street
Chicago, Illinois 60637

Subject: Secretary's Determination under Department of Health and Human Services Regulations at 45 CFR 46.407/Commissioner's Determination under Food and Drug Administration Regulations at 21 CFR 50.54 on the Research Protocol Entitled "Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty"; (Protocol #13472A, NCRR Award #M01RR00055); Principal Investigator: Dr. Robert Rosenfield

Dear Dr. Sheridan:

Thank you for your letters of September 28, 2006 and December 5, 2006. On behalf of the Assistant Secretary for Health, Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) finds that all of the stipulations outlined in OHRP's letter of May 16, 2006 have been met.

As a result, OHRP finds that the research conforms with the requirements of HHS regulations at 45 CFR part 46, subpart A, and at 45 CFR 46.407 and 46.408, and now may proceed with the HHS support provided by the National Center for Research Resources, National Institutes of Health under grant number MO1RR00055.

This concludes the 45 CFR 46.407 review process. It is the responsibility of the University of Chicago Institutional Review Board, Biological Sciences Division, to oversee the conduct of this research and to conduct continuing review of this protocol.

Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

[/s/ Bernard A. Schwetz, D.V.M., Ph.D.]

Bernard A. Schwetz, D.V. M., Ph.D.
Director
Office for Human Research Protections

cc: Dr. Robert Rosenfield, UC
Dr. Jonathan Moss, UC-IRB-BSD
Dr. Lana Skirboll, NIH
Dr. David Wilde, NCRR
Dr. Sara Goldkind, FDA
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Irene Stith-Coleman, OHRP
Dr. Kevin Prohaska, OHRP
Dr. Robert Nelson, FDA