DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 240-453-8132
FAX: 240-453-6909
E-mail: Kristina.Borror@hhs.gov

February 25, 2008

Professor Pam Fredman
Vice Chancellor
Gothenburg University
P. O. Box 100
SE 405 30 Gothenburg, SWEDEN

RE: Human Research Subject Protections Under Federalwide Assurance FWA- 848

Dear Dr. Fredman:

Thank you for your January 28, 2008 response to our March 20, 2007 letter regarding compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). We greatly appreciate your cooperation in resolving the issues related to this matter.

Based on the information submitted to us, we determine that the corrective actions taken by Gothenburg University (GU) adequately address the determinations made in our October 3, 2005 letter.

Action

In view of the above determination, we hereby reinstate the Federalwide Assurance (FWA-848) for Gothenburg University.

This reinstatement, effective immediately as of the date of this letter, provides the Assurance required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) for Federally supported research involving human subjects at the above FWA signatory institution. The FWA will retain its previous expiration date of April 11, 2008. Please ensure that the Committee for Continuing Ethical Review is registered with our office and designated on the GU FWA. Please contact Dr. Hal Blatt of our office at 240-453-8232 for more information about how to register the Committee and amend your FWA.

Recommendations

At this time, we have the following recommendation for human subjects protections at GU:

> We recommend that GU develop step-by-step descriptions with key operational details for the procedures for ensuring the prompt reporting to appropriate institutional officials, and any Department or Agency head, of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

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

Sincerely,

Kristina C. Borror, Ph.D.
Director, Division of Compliance Oversight

cc: Dr. Bo Risberg, Human Protections Administrator, GU
Dr. Olle Larko, Dean of the Sahlgrenska Academy at GU
Dr. Sherry Mills, NIH
Mr. Joseph Ellis, NIH
Commissioner, FDA
Dr. Joanne Less, FDA
Ms. Lou Valdez, OGHA