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 31, 2005

Gunnar Svedberg
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. Svedberg:

The Office for Human Research Protections (OHRP) initiated an evaluation of the Gothenburg University (GU) system for protecting human research subjects in April of 2005. The letter announcing the evaluation and requesting documents was sent to Dr. Sten Iwarson, who is the Signatory Official on the U.S. Department of Health and Human Services (HHS) GU Assurance of Compliance approved by OHRP.

An assurance of compliance is a written document submitted by an institution that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46, as well as the Terms of Assurance. Section 289 of the Public Health Service Act authorizes OHRP to, on behalf of HHS, establish a compliance oversight process regarding violations of the rights of human subjects of research conducted or supported by HHS. Pursuant to this authority, OHRP may receive reports of such violations and take appropriate action (see http://www.dhhs.gov/ohrp/compliance/ohrpcomp.pdf for a description of OHRP's compliance oversight procedures and possible outcomes of a compliance oversight evaluation.)

Dr. Iwarson has been unresponsive since OHRP requested additional information from him in our June 14, 2005 letter. In particular, OHRP notes the following:

> (1) In OHRP's June 14, 2005 letter, OHRP expressed concern about GU's apparent lack of minutes of institutional review board (IRB) meetings and written IRB procedures, as well as an apparent failure to conduct continuing review of research at least annually. OHRP requested additional information to confirm or refute these concerns by July 15, 2005.

(2) When OHRP had not heard from GU by August 5, 2005, OHRP sent an email to the signatory official on GU's assurance requesting a response to OHRP's June 14, 2005 letter to GU. The email included OHRP's letter as an attachment.

(3) When OHRP had still not heard from GU by August 23, 2005, OHRP sent faxes to both the signatory official on GU's assurance and GU's human protection administrator, requesting a response to OHRP's June 14, 2005 letter, which was enclosed. OHRP received a response from the signatory official stating "we have sent you all the answers we have to your questions."

(4) On October 3, 2005, the OHRP sent the enclosed letter to Gothenburg University (GU) regarding compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). In that letter, OHRP suspended the Gothenburg University Assurance (FWA -848) in accordance with HHS regulations at 45 CFR 46.103(e), pending satisfactory completion of the required corrective actions. The suspension of FWA-848 removed the Assurance required by HHS regulations at 45 CFR 46.103(a) for all U.S. federally supported research involving human subjects at GU covered by the FWA. **As a result, OHRP directed that all <u>U.S. federally supported</u> human subjects research projects to which the FWA applies must be suspended.**

(5) On October 18, 2005, OHRP received a letter from Dr. Iwarson. A copy of this letter is enclosed. In this letter Dr. Iwarson indicated that he could not answer OHRP's questions and directed us to take up our "problem" with the governmental ethics committee.

(6) HHS regulations at 45 CFR 46.103(c) require that an institution's assurance of compliance with the regulations for the protection of human subjects shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the regulations. In view of the above findings and observations, OHRP finds that the GU Signatory Official on the assurance has failed to fulfill his obligations imposed by the HHS regulations for the protection of human subjects and the GU FWA.

As a result, the following additional required action will be necessary for reinstatement of FWA-848:

GU must submit to OHRP a revised FWA for GU signed by a new Authorized Institutional Official. This official should reside at an administrative level above Dr. Iwarson.

OHRP notes that the noncompliance described in OHRP's October 3, 2005 letter may have resulted from deficiencies that extend beyond the institutional official who signed GU's FWA. Steps should be taken to identify and correct such deficiencies when GU's develops its corrective action plan. OHRP is available by email or telephone to discuss any issues that arise.

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. Sten Iwarson, Professor, Department of Infectious Diseases, GU
Dr. Bo Risberg, Human Protections Administrator, GU
Dr. Anders Fasth, IRB Chair, GU Hosp / East
Dr. Lana Skirboll, OD, NIH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP