



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: kborror@osophs.dhhs.gov

November 22, 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) has reviewed the Gothenburg University's (GU) November 14, 2005 email responding to OHRP's October 3 and October 31, 2005 letters regarding compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

As outlined in OHRP's October 31 and October 3, 2005 letters, the following actions are required for reinstatement of FWA-848:

- (1) GU must develop a satisfactory corrective action plan to address all deficiencies and concerns described above.
- (2) GU must submit written IRB procedures that adequately describe all activities referenced in HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5).
- (3) The IRB must submit a satisfactory plan to re-review all HHS or U.S. federally-supported human subject protocols that have not had adequate continuing review.
- (4) GU must provide a complete list of all U.S. federally supported research protocols that were suspended. Include the project title, principal investigator, IRB project number, and the Federal department or agency project number. GU should identify those projects for which GU determines that research activities in previously enrolled subjects may continue because it is in the best interests of the individual subjects. Please describe the procedures used to make such determinations.
- (5) 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 acknowledges that GU has identified U.S. federally supported research protocols; however, it appears from your email that these research protocols have not been suspended. As noted in OHRP's October 3, 2005 letter, all U.S. federally supported human subjects research projects to which the FWA applies **must be suspended**. For any project affected by this suspension, enrollment of new subjects **must cease immediately** except in extraordinary cases approved in advance by OHRP (OHRP would expect approval requests for such cases to be rare). Furthermore, research activities involving **previously enrolled subjects may continue only where it is in the best interests of such subjects**. For each affected protocol this suspension must remain in effect until OHRP approval of the FWA is reinstated. GU appears to wish to enroll new subjects and to continue research involving previously enrolled subjects. As noted above, new enrollment would only occur on a case-by-case basis with prior approval of OHRP in extraordinary, rare circumstances. GU has not provided compelling arguments for new enrollment, nor has it provided evidence that continuing previously enrolled subjects in the U.S. federally supported research protocols would be in the subjects' best interests. Therefore, OHRP reiterates all U.S. federally supported human subjects research projects to which the FWA applies **must be suspended immediately**.

OHRP acknowledges that GU is working on the other requirements for reinstatement of the FWA. Until those requirements are completed to OHRP's satisfaction, the GU assurance, **FWA- 848, remains suspended**.

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. Borrer, 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