DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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November 8, 2006

Philip Rosenthal
Vice President of Operations
Lenox Hill Hospital
100 East 77th St.
New York, NY 10021

RE: Human Research Subject Protections Under Federalwide Assurance FWA 641

Research Project: Research Involving Colonoscopies and Endoscopies of Autistic Children
Principal Investigator: Dr. Arthur Krigsman

Dear Mr. Rosenthal:

The Office for Human Research Protections (OHRP) has reviewed the Lenox Hill Hospital's (LHH) February 7, 2006 response to OHRP's December 5, 2005 letter regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

Based on review of your report, OHRP notes the following:

(1) The LHH December 5, 2005 report states:

(a) "During 2001 and 2002, Dr. Krigsman submitted three research proposals to the Lenox Hill IRB [institutional review board] relating to studies of gastrointestinal symptoms of autistic children. None of these proposals was approved by the IRB."

(b) "... the IRB was made aware that on June 19, 2002, Dr. Krigsman had testified before the United States House of Representatives Committee on Government Reform on 'The Status of Research into Vaccine Safety and Autism.' In his

testimony, Dr. Krigsman referred to a retrospective study he had done, and testified that he had 'collected intestinal biopsy specimens from 43 patients,' and that he was 'waiting for ... formal IRB approval' for his research."

(c) "The IRB had not approved and never approved any study proposed by Dr. Krigsman, and Dr. Krigsman's first proposal had been rejected because of concerns about risks to the subjects."

(d) "The IRB was unable to determine that Dr. Krigsman had obtained the biopsies through documented medically necessary procedures, and was fearful that Dr. Krigsman had been performing these procedures to support his research."

(e) "In February 2003, the Department of Pediatrics commenced a quality of care review of Dr. Krigsman's practice. The Departmental Ad Hoc Review Committee ('Ad Hoc Committee') was charged with investigating three allegations of Dr. Krigsman's practice that would warrant corrective action: (1) a lack of documentation of the medical necessity for performing colonoscopies and endoscopies on autistic children; (2) lack of documentation of medical necessity for doing multiple biopsies; and (3) conducting clinical research without IRB approval."

(f) "The Ad Hoc Committee found that Dr. Krigsman's medical charts lacked adequate documentation, but stated that, *assuming Dr. Krigsman was accurately describing the signs and symptoms in his patients and the extensive evaluation he gave each patient in his office before performing the procedure*, 'there appears to be clinical indication for the procedures and the biopsies.'" [Emphasis in original]

(g) "On the concern that Dr. Krigsman was conducting unapproved research, the report noted:

> There is no evidence that Dr. Krigsman is doing clinical research without an IRB approval. However, it is clear that he is in a gray zone of knowledge, and probably should be operating in the context of a clear protocol with IRB approval to maximize the clinical data being collected and further the investigation into an ill-defined entity."

(h) "Based on the recommendations of the Ad Hoc Committee, in early June 2003 the Lenox Hill Medical Board asked Dr. Krigsman to provide the Ad Hoc Committee with the Medical charts of 10 randomly selected patients. Dr. Krigsman refused to provide medical charts from his office..."

(i) "Dr. Krigsman's refusal to provide patient medical charts for review by the Ad Hoc Committee ... frustrated any further investigation by Lenox Hill of his alleged research activities."

(j) "*... since his resignation from the Lenox Hill medical staff on December 31, 2004, Dr. Krigsman has not performed any endoscopic procedures at Lenox Hill.* Because of his resignation, he cannot see any patient at Lenox Hill." [Emphasis in original]

(2) It was alleged that the investigator conducted research involving colonoscopies and endoscopies on children with autism without IRB review and approval, as required by HHS regulations at 45 CFR 46.103 (b) and 46.109(a). Based on the above information, OHRP is unable to make a determination regarding this allegation.

(3) It was alleged that the LHH IRB failed to ensure that additional safeguards were included to protect the rights and welfare of vulnerable subjects, as required by HHS regulations at 45 CFR 46.111(b). OHRP finds that this allegation could not be substantiated.

As a result of the above determination and the fact that the investigator is no longer able to see patients at LHH, OHRP anticipates no further involvement in this matter.

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,

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

cc: Mr. Sahan Boorboor, IRB Administrator, LHH
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