



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8120
Fax: 240-453-6909
E-mail: lisa.rooney@hhs.gov

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Barry S. Arbuckle, Ph.D.
President/Chief Executive Officer
Memorial Health Services
MHS Corporate Office
2801 Atlantic Ave.
Long Beach, CA 90806

RE: Human Research Protections Under Federalwide Assurance FWA-81

Research Project: Research Involving Flexible Bronchoscopy on Children Experiencing Asthma and/or Respiratory Failure

Principal Investigator: Dr. J. Carlos Maggi

Dear Dr. Arbuckle:

Thank you for your August 13, 2007 report in response to the OHRP July 6, 2007 request that Memorial Health Services (MHS) evaluate allegations of noncompliance with Department of Health and Human Services regulations for the protection of human research subjects (45 CFR part 46).

As you are aware, the complainants alleged that the investigator referenced above engaged in non-exempt human subjects research when he performed flexible fiberoptic bronchoscopy procedures on intubated and non-intubated status asthmaticus patients who were admitted into the Miller Children's Hospital pediatric intensive care unit between 1997 and 2003 without seeking prior institutional review board (IRB) review and approval for such research activities. Based on the information provided, we make the following determinations:

- (1) We note that the Memorial Health Services Research Inquiry Committee (MHSRIC) determined that the data were collected as part of what the investigator believed to be optimal clinical care. We note the following from your August 13, 2007 report:

“No procedures, including the bronchoscopies, were performed solely for the purposes of a research project, no separate research files were maintained (distinct from the involved subject's medical records) and no additional visits were performed as part of the research activity. Each subject was consented for each of the described procedures (including

bronchoscopy) and no allocation of subjects (such as randomization) occurred based upon research hypotheses.”

Based on the documentation provided in your August 13, 2007 correspondence, we have determined that this allegation of noncompliance is unproven. No evidence was presented to us indicating that performance of flexible fiberoptic bronchoscopy procedures on intubated and non-intubated status asthmaticus patients constituted a research intervention.

- (2) We acknowledge the MHSRIC’s findings of noncompliance and the ensuing corrective actions noted in the August 13, 2007 report. In specific, we note that MHSRIC found that the investigator’s retrospective chart review activities did constitute research and should have been submitted to, and approved by, the MHS Research Council (IRB) before the data were collected, analyzed, or presented in the research forums.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate your institution’s continued commitment to the protection of human research subjects.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Harris R. Stutman, Executive Director, Research Administration, MHS
Dr. Houchang Modanlou, Chairperson, MHS IRB
Dr. J. Carlos Maggi