



Office for Human Research Protections
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March 24, 2003

Ralph Snyderman, M.D.
President
Duke University Health Systems, Inc.
Box 3701
Durham, NC 27710

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1106

Research Project: Mini-Gastric Bypass Surgery for Weight Loss
Principal Investigator: Dr. Robert R. Rutledge

Dear Dr. Snyderman:

The Office for Human Research Protections (OHRP) has reviewed the Duke University Health System's (DUHS) April 25, 2002 report submitted in response to OHRP's March 7, 2002 letter regarding the above-referenced research.

OHRP notes that DUHS's April 25, 2002 report stated the following:

(1) "In December 1998, Dr. Rutledge was first appointed to the staff of DRH [Durham Regional Hospital] and specifically credentialed to perform the MGB [Mini-Gastric Bypass] procedure that he had developed at another academic health center."

(2) "At no time was Dr. Rutledge a faculty member of the Duke School of Medicine. Also, he was not employed by Durham Regional Hospital."

(3) "In the case of the MGB, DRH considered the procedure to be an accepted practice upon credentialing Dr. Rutledge to perform this procedure."

- (4) "The MGB procedure was the only procedure Dr. Rutledge provided to patients desiring surgical treatment of extreme obesity, and he had sought and received privileges at DRH that were specific to that procedure."
- (5) "Our review of this matter leads to the conclusion that Dr. Rutledge was providing care to his patients at DRH using the treatment modality he favored (and used exclusively), and was not engaged in any research activity in performing the MGB procedure."
- (6) "DUHS recognizes that regulated 'research' includes the retrospective analysis of existing patient data (unless the exemption at 45 CFR § 46.101(b)(4) applies). However, Dr. Rutledge did not request medical records from the DRH Medical Records Department in a manner that would have indicated that DRH's resources were being used in connection with possible research activity."
- (7) "Dr. Rutledge's independent collection and analysis of aggregated data in connection with MGB procedure patients was undertaken using records that he personally developed and maintained as opposed to records in the custody of DRH. His activities in that regard were not research in which DRH or DUHS was engaged."

Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) require that each institution "engaged" in human subjects research provide OHRP with a satisfactory Assurance to comply with the regulations, unless the research is exempt under 45 CFR 46.101(b). An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. OHRP finds that DUHS was not "engaged" in human subjects research involving the MGB procedure performed by Dr. Rutledge, and as a result, OHRP does not have jurisdiction in this matter.

As a result of the above determinations, there should be no need for further involvement of OHRP 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

March 24, 2003

cc: Dr. John Falletta, Chair IRB 1, DUHS
Dr. Joseph Farmer, Chair IRB 2, DUHS
Dr. George Parkerson, Chair IRB 3, DUHS
Dr. Vance Singletary, Chair IRB 4, DUHS
Ms. Charlotte Coley, Director, IRB Educational Programs, DUHS
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