



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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

Telephone: 240-453-8298
FAX: 240-453-6909
E-mail: Lisa.Buchanan@HHS.gov

September 6, 2010

F. Richard Bringhurst, M.D.
Sr. Vice President of Med. & Research Management
Massachusetts General Hospital (MGH)
Bullfinch Building
55 Fruit Street
Boston, MA 02114

RE: Human Research Protections under Federalwide Assurance FWA-3136

Research Project: A Novel, Population-based Prospective Inception Cohort of Inflammatory Bowel Syndrome. Ocean State Crohn's and Colitis Area Registry (OSCCAR)

MGH Principal Investigator: Bruce Sands, M.D.

NIH Grant Number: 5R21DK078555-02

Dear Dr. Bringhurst:

Thank you for your December 14, 2009 and May 24, 2010 reports in response to the Office for Human Research Protections' (OHRP) October 30, 2009 request that Massachusetts General Hospital (MGH) investigate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

We acknowledge that MGH is the prime awardee institution for this research, but all activities involving human subjects are carried out at Rhode Island Hospital (RIH); and MGH and RIH IRBs conducted a joint review of this research in accordance with HHS regulations at 45 CFR 46.114. Per your response, MGH's IRB reviewed only the protocol, and MGH relied on RIH's IRB to review the informed consent or recruitment documents for the above research. We note that when we initiated this investigation, the MGH FWA did not designate RIH's IRB as an IRB permitted to review human subjects research under the assurance; however, we acknowledge that MGH subsequently updated its FWA to designate RIH's IRB in compliance with the joint

review agreement outlined in your response. We are continuing our evaluation of this matter with RIH. There should be no need for further involvement with MGH by our office in this matter as:

1. MGH's role in this research is as the prime awardee of the research grant and MGH receives de-identified data for analysis only; and
2. MGH held an authorization agreement with the IRB of a FWA-holding institution for the IRB review and oversight of the human subject research activities.

We appreciate your investigation into the matters outlined in our initial request and your responses to the questions and concerns we raised in our May 3, 2010 letter. We determine that your responses adequately address those questions and concerns and are appropriate under the MGH FWA.

We appreciate 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,

Lisa R. Buchanan, MAOM
Compliance Oversight Coordinator
Division of Compliance Oversight

cc:

Ms. Maria Sundquist, Human Protections Administrator, MGH
Dr. Elizabeth Hohmann, Chairperson, IRB #1, MGH
Dr. Diane Carroll, Chairperson, IRB #2, MGH
Dr. David Smith, Chairperson, IRB #3, MGH
Dr. James Linakis, Chairperson, Lifespan IRB/RIH #1
Dr. Jennifer Friedman, Lifespan IRB/RIH Panel #2
Ms. Patricia E. Houser, Manager, Lifespan IRB/RIH
Dr. Griffin P. Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases
Dr. Marilyn S. Radke, Director, OSRS, Centers for Disease Control
Dr. Sherry Mills, National Institutes of Health
Mr. Joseph Ellis, National Institutes of Health