



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

May 4, 2011

Peter J. Snyder, PhD
Vice President Clinical Research
Rhode Island Hospital
593 Eddy Street
Aldrich Building Suite 132
Providence, RI 02903

RE: Human Research Protections under Federalwide Assurance FWA-1230

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

RIH Principal Investigator: Samir Shah, MD

Sub Recipient: Rhode Island Hospital

Prime Awardee: Massachusetts General Hospital

NIH Grant Number: 5R21DK078555-02

Dear Dr. Snyder:

Thank you for your June 9, 2010 and February 18, 2011 reports in response to the Office for Human Research Protections' (OHRP) request that Rhode Island Hospital (RIH) 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 Massachusetts General Hospital is the prime awardee institution for this research, but all activities involving human subjects were carried out at RIH; and MGH and RIH IRBs conducted a joint review of this research in accordance with HHS regulations at 45 CFR 46.114.

In our January 12, 2011 letter, we made the following determination:

- (1) We determined that the study website and a description of the proposed content should have been reviewed by the IRB prior to its activation in accordance with HHS regulations at 45 CFR 46.103(b)(4)(iii) which require that the IRB review and approve all proposed changes in a research activity during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects.

Corrective Action: We acknowledge that the IRB revised its initial application and continuing review report to clarify which recruitment tools will be used as part of a research study. We note that the Communication Department has also modified its procedures to ensure that IRB review and approval is obtained prior to making any recruitment material available to the public.

- (2) We determined that your institution inappropriately exempted human subjects research which resulted in the conduct of human subject research without obtaining legally effective informed consent of subjects and without the IRB appropriately waiving these requirements in violation of HHS regulations at 45 CFR 46.116(c) or (d). Specifically, the protocol reviewed by the IRB included a section titled "Identification of Unreferred Incident Cases" that required researchers to collect information from medical records about individuals that were diagnosed with Irritable Bowel Syndrome, but did not enroll in this study--"to get accurate incidence rates." The IRB exempted this part of the protocol and did not waive or require that informed consent be obtained from those subjects. However, HHS regulations at 45 CFR 46.101(b)(4) exempt research that only involves the collection or study of *existing* data, documents, records, pathologic specimens, or diagnostic specimens provided specified conditions are met, and in this case the records did not exist at the time the research was proposed.

Further, the IRB should have reviewed the protocol as submitted as a single study, as opposed to reviewing the "Identification of Unreferred Incident Cases" section separately as if it were an independent study.

Corrective Action: We acknowledge that your institution has revised its forms and procedures to ensure that your institution appropriately applies HHS regulations at 45 CFR 46.101(b)(4) in making exemption determinations, and conducts human subject research with the legally effective informed consent of subjects, unless the IRB appropriately waives these requirements in accordance with HHS regulations at 45 CFR 46.116(c) or (d).

We determine that these corrective actions adequately address our determinations and are appropriate under the Rhode Island Hospital FWA. At this time, there should be no need for further involvement by our office in this matter.

We appreciate the continued commitment of your institution to the protection of human research

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subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Lisa Buchanan, MAOM
Division of Compliance Oversight

cc:

Dr. James Linakis, Chairperson, Lifespan IRB/Rhode Island Hospital

Ms. Patricia E. Houser, Manager, Lifespan IRB/Rhode Island Hospital

Dr. F. Richard Bringhurst, Sr., VP of Medicine & Research Management,
Massachusetts General Hospital

Dr. Griffin P. Rodgers, Director, National Institute of Diabetes and Digestive and Kidney
Diseases (NIDDK)

Dr. Marilyn S. Radke, Director, OSRS, Centers for Disease Control

Dr. Sherry Mills, National Institutes of Health

Mr. Joseph Ellis, National Institutes of Health