DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the Assistant Secretary for Health

Office for Human Research Protections
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August 14, 2012

William T. Morgan, PhD
Interim Vice Provost for Research
University of Missouri, Kansas City
Office of Research Services
5211 Rockhill Road
Kansas City, MO 64110

RE: Human Research Protections Under Federalwide Assurance FWA-5427

Grant Number	PI Name	Project Title
5P50AR055081-020001	DENG, HONG-WEN	GenomeWide Scans for Female Osteoporosis Risk Genes
5P50AR055081-020002	DENG, HONG-WEN	Genome-wide and Specific Gene Expression
5P50AR055081-020003	DENG, HONG-WEN	Proteome-wide Expression Study of Osteogenesis
5P50AR055081-029001	DENG, HONG-WEN	Clinical Core
5P50AR055081-029002	DENG, HONG-WEN	Biostatistics and Bioinformatics Core
5R01AG026564-02	DENG, HONG-WEN	Genomic search for bone mass QTLs
5R01AR050496-05	DENG, HONG-WEN	Robust and Powerful Test of Candidate Genes to Bone Mass
5R21AG027110-02	DENG, HONG-WEN	Proteomics Study of Peripheral Blood Monocytes on Osteoporosis

Dear Dr. Morgan:

Thank you for your April 6, 2012 report in response to our February 13, 2012 request that University of Missouri, Kansas City (UMKC) evaluate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on review of your response, we make the following determinations:

A. Determinations regarding the above-referenced research

The complainant alleged that the institutional review board (IRB) required the investigator to stop recruiting for the study "The Kansas City Osteoporosis Study (KCOS)" due to research being conducted without IRB review and approval, and to destroy all data and samples obtained prior to IRB approval; however, the data and samples were not destroyed and continued to be used for research purposes. Based on the documentation provided in your April 6, 2012 correspondence, we have determined that the allegations of noncompliance are unproven. While your response confirms that the IRB required the investigator to stop recruiting due to research being conducted without IRB review and approval, and to destroy all data and samples obtained prior to IRB approval, no evidence was presented to us indicating that the data and samples were not destroyed and continued to be used for research purposes. You indicated that, to the best of your knowledge, the data and samples were indeed destroyed in the presence of an IRB administrator and provided OHRP a copy of a document signed by Dr. Deng to that effect. A later investigation of this research revealed concerns about training of research staff and privacy and confidentiality of study procedures, which were addressed by the institution prior to OHRP receiving the allegations.

Please note that serious or continuing noncompliance and suspensions or terminations of IRB approval must be reported to OHRP as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5). We have no record of receiving a report of the suspension of this study or the serious/continuing noncompliance. We recommend that your institution enhance your procedures for ensuring such events are reported to OHRP.

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 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,

Kristina C. Borror, Ph.D.
Director, Division of Compliance Oversight

cc:
Ms. Sheila Anderman, Manager, Research Protections, University of Missouri - Kansas City
Dr. Roger Sommi, Jr, IRB Chairperson, University of Missouri, Kansas City IRB #1

Dr. Mary O'Connor, IRB Chairperson, University of Missouri-Kansas City IRB #3
Dr. Hong-Wen Deng, University of Missouri-Kansas City

Dr. Sherry Mills, National Institutes of Health (NIH)
Mr. Joseph Ellis, NIH
Dr. Stephen I. Katz, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases
Dr. Richard Hodes, Director, National Institute on Aging