



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: 240-453-8132  
FAX: 240-453-6909  
E-mail: [Lisa.Buchanan@hhs.gov](mailto:Lisa.Buchanan@hhs.gov)

June 20, 2011

Cheryl Potgieter, PhD  
University Dean of Research  
University of KwaZulu-Natal  
Research Office  
Private bag X54001  
Durban, KwaZulu Natal 4000 SOUTH AFRICA

Thomas Moore, M.D.  
Associate Provost  
Boston University Medical Center  
715 Albany Street, Evans Bldg. 7  
Boston, MA 02118-2526

**RE: Human Research Protections Under Federalwide Assurance FWA-301 and FWA-678**

**Research Project: The Amajuba Child Health and Wellbeing Research Project**  
**Principal Investigator: Prof. T. Quinlan**  
**HHS Protocol Number: 5R24HD043629-05**

Dear Drs. Potgieter and Moore:

Thank you for your September 10 and 29, 2010 reports in response to our August 9, 2010 request that Boston University Medical Center (BUMC) and University of KwaZulu-Natal (UKZN) 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 appreciate your investigations into the matters outlined in our request.

**A. Determinations regarding the above-referenced research.**

(1) It was alleged, and we determine, that questionnaires with identifiers were shipped to a third party (the Centre for Research on Evaluation, Science and Technology (CREST), University

of Stellenbosch), in violation of the protocol, informed consent document, and HHS regulations at 45 CFR 46.103(b)(4)(iii) & 116(a)(5). Specifically, the informed consent and assent state that “[o]nly core research team members will have access [to subject data]. Only researchers of the University of Kwazulu Natal and Boston University may use the files as part of their job to oversee the study.”

We acknowledge that Boston University (BU) is not the primary grant recipient for this research and that BU’s engagement was primarily with the longitudinal household survey that was completed in 2007. BU had no control over the alleged data and did not release any data to CREST.

UKZN’s response indicates that “after the collection of the data, an issue beyond the control of UKZN arose in respect of the analysis of the data – the data was not analyzed according to the agreed time.” To address this problem, UKZN decided to add “CREST as a member of the of Project team...due to its experience in conducting data analysis and handling data...” Based on the documentation provided, this change was made without prior IRB review or approval in violation of 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. Research subjects also were not informed that CREST would have access to their records, in violation of HHS regulations at 45 CFR 46.116(a)(5).

**Required Action:** Please provide a corrective action plan that the IRB will use to ensure compliance with HHS regulations at 45 CFR 46.103(b)(4)(iii) & .116(a).

## **B. Questions and Concerns**

(1) [Redacted]

(2) [Redacted]

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(3) [Redacted]

Please provide responses to the above determination, questions and concerns by July 29, 2011. If you identify any areas of noncompliance in reviewing the above determination concerns, please describe corrective actions that you have taken or plan to take to address the noncompliance. Also, if you have any questions or if you need assistance in developing any corrective action plan, please feel free to contact us.

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

Sincerely,

Lisa R. Buchanan, M.A.  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc:

Dr. Douglas R. Wassenaar, BREC Research Office, UKZN  
Mr. Jagidesa Moodley, Chairperson, UKZN IRB  
Prof. T. Quinlan, UKZN  
Ms. Mary Banks, IRB Director, BUMC  
Dr. Jonathan Woodson, IRB Chairperson/Assoc Chief Med Officer, BUMC IRB Green  
Dr. James Feldman, IRB Chairperson, BUMC IRB Blue  
Dr. Michael Lyons, IRB Chairperson, BUMC IRB  
Dr. Sanford Auerbach, IRB Chairperson, BUMC IRB Purple

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Dr. Sherry Mills, National Institutes of Health (NIH)

Mr. Joseph Ellis, NIH

Dr. Alan E. Guttmacher, Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Ms. Susan Newcomer, Demographic & Behavioral Sciences (DBS) Branch, NICHD