



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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November 10, 2011

Cheryl Potgieter, PhD
University Dean of Research
Research Office, University of KwaZulu-Natal
Westville Campus, Govan Mbeki Building
Private bag X 54001
Durban
4000
KwaZulu Natal, SOUTH AFRICA

RE: Human Research Protections Under Federalwide Assurance FWA-678

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

Dear Dr. Potgieter:

Thank you for your August 30, 2011 report in response to our June 20, 2011 determination letter regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

In our June 20, 2011 letter, we determined that the questionnaires shipped with subject identifiers to a third party (Centre for Research on Evaluation, Science and Technology (CREST), University of Stellenbosch), was not consistent with the IRB approved protocol and consent document, 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. 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.”

Further, we determined that the fact that subjects were not informed that CREST would have access to their questionnaires to conduct data analysis constituted a violation of HHS regulations at 45 CFR 46.116(a)(5), which require that consent documents include a statement describing the extent to which confidentiality of records identifying the subject will be maintained.

Corrective Action: We acknowledge that UKZN IRB's Terms of Reference and Standard Operating Procedures (ToR & SoP) have now been "extensively reviewed and revised [in compliance with] 46.103(b)(4)(iii) & .116(a)." Further, UKZN IRB members, the research community and IRB administrative staff are aware of the revised ToR & SoP, and the revised documents have been posted on your website.

We determine that your responses adequately address our questions and concerns, and the corrective actions described above both adequately address our determinations and are appropriate under the UKZN 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 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:

Dr. Douglas R. Wassenaar, BREC Research Office, UKZN
Mr. Jagidesa Moodley, Chairperson, UKZN IRB
Prof. T. Quinlan, UKZN
Dr. Thomas Moore, Associate Provost, Boston University Medical Center (BUMC)
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