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: 240-453-8120
FAX: 240-453-6909
E-mail: Lisa.Rooney@hhs.gov

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Cheryl Potgieter
Dean of Research
University of KwaZulu-Natal
Nelson R. Mandela School of Medicine
Private Bag X54001
Durban, KwaZulu Natal 4013
SOUTH AFRICA

**RE: Human Research Subject Protections Under Federalwide Assurance (FWA) – 678**

Dear Ms. Potgieter:

Thank you for your January 22, 2009 letter in response to our December 16, 2008 letter regarding our evaluation of your institution's system for protecting human research subjects.

A. In our August 13, 2008 letter we determined that the University of KwaZulu-Natal (UKN) failed to have the following written Institutional Review Board (IRB) procedures as required by Department of Health and Human Service (HHS) regulations at 45 CFR 46.103(a), 45 CFR 46.103(b)(4), and 45 CFR 46.103(b)(5). Subsequently, in our letter dated December 16, 2008 we requested that UKN provide us with final versions of the Biomedical Research Ethics Committee (BREC) Terms of Reference (hereinafter referred to as Terms of Reference) and BREC Standard Operating Procedures (SOPs) referencing the following procedures:

(1) The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution;

(2) The procedures which the IRB will follow for determining which projects require review more often than annually;

(3) The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

(4) The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and

(5) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

**Corrective Action**: UKN provided us with final versions of the BREC Terms of Reference and SOPs. We determine that these final written procedures are adequate and appropriate under the UKN FWA.

B. In our December 16, 2008 letter we determined that UKN IRB failed to satisfy the quorum requirements for its November and December 2007 IRB meetings as required by HHS regulations at 45 CFR 46.108(b).

**Corrective Action**: We acknowledge that UKN amended its BREC SOPs to comply with the quorum requirements of 45 CFR 46.108(b). In addition, we acknowledge that UKN will re-review all HHS-supported research that was reviewed during the November 2007 and December 2007 IRB meetings. We determine that these corrective actions are adequate and appropriate under the UKN FWA.

We acknowledge the remaining responses to the questions, concerns and recommendations noted in our December 16, 2008 letter which was provided in your January 22, 2009 letter.

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

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator

cc: Dr. Jagidesa Moodley, Administrator, Biomedical Research Ethics, U KwaZulu-Natal
Acting Commissioner, Food and Drug Administration (FDA)
Dr. Joanne R. Less, FDA
Dr. Sherry Mills, National Institutes of Health (NIH), Office of Extramural Research
Mr. Joe Ellis, NIH, Office of Extramural Research
Dr. Doug Wassenaar, Chair, UKN Biomedical Research Ethics Committee Chair