DEPARTMENT OF HEALTH & HUMAN SERVICE

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: 301-453-8120
Fax: 301-453-6909
E-mail: Lisa.Rooney@hhs.gov

February 21, 2008

Albert L. Walker, Ed.D.
President
Bluefield State College
219 Rock Street
Bluefield, WV 24701

**RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 10457**

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|---|---|
| **Research Project:** | Socio-Cultural Determinants of Utilization of Breast Cancer Awareness and Prevention Services Among African-American Women in Southern West Virginia (hereinafter referred to as the Breast Cancer Study) |
| **Principal Investigator:** | Anthony T. Woart, Ph.D. |
| **Research Project:** | Characterization of Molecular Diversity of HIV Sub-Types and Inter-Subtypes Recombinants Among African-Americans (hereinafter referred to as the HIV Study) |
| **Principal Investigator:** | Edward Omolo, Ph.D. |
| **Research Project:** | Identification of at Risk African-American Adolescents for Type 2 Diabetes and the Role of Screening in Early Detection (hereinafter referred to as the Type 2 Diabetes Study) |
| **Principal Investigator:** | Martha Eborall, Ph.D. |
| **HHS Grant Number:** | **RFA-MD-04-002/1R24 MD001107-01** |

Dear Dr. Walker:

Thank you for your January 14, 2008 report in response to our July 9, 2007 and September 17, 2007 letters regarding research conducted under the above-referenced Federalwide Assurance (FWA). Based on this most recent correspondence (and a January 29, 2008 telephone conversation with the Bluefield State College (BSC) Human Protections Administrator (HPA)) all previously identified corrective actions have been replaced with BSC's most recent corrective action, i.e., the designation of another institutional review board (IRB) to review research to which the BSC FWA applies. According to the BSC HPA, BSC will now follow the written procedures of the designated IRB and it is BSC's belief that these procedures adequately address all the determinations to date.

In our July 9, 2007 letter, we made the following determinations:

(1) We determined that BSC did not have a duly constituted, functioning IRB until Fall 2006 at the earliest, and that a BSC IRB did not conduct initial or continuing review of the above-referenced research prior to Fall 2006 at the earliest, in contravention of the requirements of Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b), 46.109(a), and 46.109(e).

(2) We determined that the BSC IRB, which was constituted as of Fall 2006 and consisted of members appointed by you, did not include at least one member who is not otherwise affiliated with BSC and who is not part of the immediate family of a person who is affiliated with BSC as required by HHS regulations at 45 CFR 46.107(d).

(3) We determined that, from the evidence before us, that the BSC IRB had not made the findings required under HHS regulations at 45 CFR 46.404-.407 when reviewing the Type 2 Diabetes Study, which involved children.

(4) We determined that, from the evidence before us, that the BSC IRB had not reviewed the HHS grant application referenced above prior to the initiation of research, as required by HHS regulations at 45 CFR 46.103(f).

(5) We determined that the person identified as the BSC IRB Chairperson in July 2007 lacked a detailed understanding of the specific requirements of the HHS regulations for the protection of human subjects.

**Corrective Action**: We acknowledge that BSC has designated the Western IRB to review all non-exempt human subjects research falling under the BSC FWA. We note that, in accordance with the requirements of 45 CFR 46.1103(b)(2), the Western IRB has been established in accordance with the requirements of the HHS protection of human subjects regulations, and provisions have been made for meeting space and sufficient staff to support Western IRB's review and recordkeeping duties. We note

further that BSC will follow the written IRB procedures of the Western IRB. We find that this corrective action adequately addresses the above determinations. Once implemented, please provide us with a copy of the written IRB procedures (as outlined in HHS regulations at 45 CFR 46.103(b)(4) and (b)(5)) that BSC will follow.

In our September 17, 2007 letter, we made the following additional determinations:

(6) We determined that the revised Type 2 Diabetes informed consent documents, i.e., research subject information and consent form for adults (for subjects between the ages of 18 and 20) and research subject information and consent form for subjects that require parental consent (for the parents of subjects between the ages of 10 and 18), and the revised informed consent document for the Breast Cancer Study did not include basic elements of informed consent as required by HHS regulations at 45 CFR 46.116(a).

**Corrective Action**: We acknowledge that BSC investigators and BSC IRB members participated in training sessions that included a tutorial on the basic elements of informed consent as outlined in HHS regulations at 45 CFR 46.116(a). Moreover, we note that BSC investigators will now be required to follow the written procedures/guidelines/checklists provided by the Western IRB, the IRB that BSC has designated under the BSC FWA. Lastly, we note that this study is complete. As a result, we find that these corrective actions adequately address this determination.

(7) We determined that BSC does not have written procedures adequately describing the following IRB activities, as required by 45 CFR 46.103(b)(4) and (5):

(a) procedures which the IRB will follow for reporting its findings and actions to the institution.

(b) procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of:

(i) any unanticipated problems involving risks to subjects or others (hereinafter referred to as *unanticipated problems*);
(ii) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
(iii) any suspension or termination of IRB approval.

**Corrective Action:** We acknowledge that BSC intends to rely on the written procedures of the Western IRB, the IRB that BSC designated under the BSC FWA. We find that this corrective action adequately addresses our determination.

In light of the corrective actions implemented by BSC, we hereby reinstate the Federalwide Assurance (FWA-10457) for BSC. This reinstatement, effective as of the date of this letter, provides the Assurance required by HHS regulations at 45 CFR

46.103(a) for Federally supported research involving human subjects at the above FWA signatory institution. The FWA will retain its previous expiration date of January 15, 2011. Moreover, please be advised that this compliance oversight case is now closed. As a result, there should be no need of further involvement of our office in this matter.

We appreciate the continued commitment of your institution to the protection of human research subjects. Do not hesitate to contact me should you have any questions.

Sincerely,

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

cc: Dr. Tracey K. Anderson, Director of Institutional Research and Effectiveness, BSC
Dr. Anthony T. Woart, BSC
Dr. Martha Eborall, BSC
Ms. Sherry Mills, OER, NIH
Mr. Joe Ellis, OER, NIH
Dr. Andrew C. von Eschenbach, FDA Commissioner
Dr. Joanne R. Less, FDA