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**RE: Human Research Protections Under Federalwide Assurance FWA-13698**

**Research Project: Native American Cancer Education for Survivors (NACES)**

**Principal Investigator: Dr. Linda Burhansstipanov**

**HHS Protocol Number:1 R25 CA 101938-01A1**

Dear Dr. Seals, Dr. Burhansstipanov and Ms. Wishon:

Thank you for your responses to our letter of October 8, 2008 which forwarded a complainant's allegations of noncompliance with Department of Health and Human Services (HHS) regulations

for the protection of human research subjects (45 CFR Part 46) with respect to the Native American Cancer Education for Survivors (NACES) research project.

Determinations regarding the above-referenced research

The complainant alleged that the following protocol changes were implemented without institutional review board (IRB) review and approval as required by HHS regulations at 45 CFR 46.103(b)(4)(iii):

- (1) failure to enroll interested subjects from the National Native American Cancer Survivors' Support Network;
- (2) enrollment of non-native subjects and individuals who never diagnosed with cancer; and
- (3) enrollment of children into the study.

We acknowledge that the Colorado Multiple Institutional Review Board (COMIRB) was the IRB of record for the NACES study and that COMIRB determined that the study was exempt from IRB review under HHS regulations at 45 CFR 46.101(b)(1), which exempts research conducted in established or commonly accepted educational settings involving normal educational practices.

As NACES was exempt from the HHS regulatory requirements for IRB review and approval under 45 CFR 46.101(b)(1), we determine that COMIRB was not obligated to review and/or approve the three alleged protocol changes to NACES identified above.

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 institutions to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.  
Division of Compliance Oversight

cc: Mr. Stephen Bartlett, Chair, COMIRB Panel D  
Dr. Sherry Mills, National Institutes of Health  
Mr. Joseph Ellis, National Institutes of Health  
Dr. John E. Niederhuber, Director, National Cancer Institute