



Office for Human Research Protections  
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August 10, 2011

David S. Carlson, Ph.D.  
Vice President for Research and Graduate Studies  
The Texas A&M University System Health Science Center  
147 Reynolds Medical Building  
College Station, TX 77843-1114

**RE: Human Research Protections Under Federalwide Assurance (FWA) - 5869**

**Research Project: Effects Of Nicotine in Smokers With Anxious Mood**  
**Principal Investigator: Sandra Morissette**  
**HHS Protocol Number: 7K23DA016376-06**

Dear Dr. Carlson:

Thank you for your December 6, 2010 letter and May 16, 2011 email in response to our November 2, 2010 letter in which we asked you to investigate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research. Based on the information submitted, we make the following determination:

A complainant alleged that files containing identifiable private information of subjects were being stored in an unsecured manner and were improperly redacted in violation of HHS regulations at 45 CFR 46.111(a)(7).

We acknowledge that the Texas A&M University System Health Science Center (Texas A&M) conducted an investigation regarding these allegations and found no basis for the allegations. In specific, we note the following:

- (1) Individuals/researchers on site at the Waco Veterans Affairs (VA) Center of Excellence have password protected computers;
- (2) Identifiable paper data are stored in locked filing cabinets in a locked office with limited access;
- (3) The electronic databases that were examined as part of this investigation contained de-identified data;

- (4) That a back up copy of the database is kept on CD in the principal investigator's desk, under lock and key, and the database on the CD is password protected;
- (5) While the data collection tool contains protected health information (PHI), as initially approved by the Boston VA Institutional Review Board (IRB), such data was subsequently blacked out by the principal investigator after the Boston VA IRB asked that such information no longer be collected; and
- (6) Such data collection tools are kept in locked cabinets in a locked office with limited access and are not treated as de-identified data.

Given the above, we have determined that these allegations of noncompliance are unproven. No evidence was presented to us indicating that files containing identifiable private information of subjects were being stored in an unsecured manner or were improperly redacted in violation of HHS regulations at 45 CFR 46.111(a)(7).

We acknowledge the findings that Texas A&M uncovered while conducting its investigation into the allegations noted above. The corrective action outlined in the December 6, 2010 letter satisfactorily addresses these findings and is appropriate under the terms of the Texas A&M FWA.

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 institution to the protection of human research subjects.

Sincerely,

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

cc: Ms. Lindsay T. Newcomer, Program Coordinator- Research Compliance, Texas A&M  
University System Health Science Center  
Dr. Sherry Mills, National Institutes of Health (NIH)  
Mr. Joseph Ellis, NIH