



Office for Human Research Protections
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November 27, 2006

Fernando A. Guerra, M.D., M.P.H.
Director of Public Health
San Antonio Metropolitan Health District
322 West Commerce
San Antonio, TX 78205

RE: Human Research Subject Protections Under Federal Wide Assurance (FWA)-1979

**Project Title: San Antonio Metropolitan Health District 2nd Phase Kelly Air Force Base
Environmental Health Screening Project (KAFBEHSP)
Principal Investigator: Fernando A. Guerra, M.D., M.P.H.
Project Number: WIRB 20011823**

Dear Dr. Guerra:

The Office for Human Research Protections (OHRP) has reviewed the San Antonio Metropolitan Health District (SAMHD) November 1, 2005 and September 26, 2006 responses to OHRP's September 27, 2005 letter regarding indications of possible 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 project.

Based upon its review, OHRP makes the following determinations:

- (1) In accordance with HHS regulations at 45 CFR 46.103(b) and 46.109(a), the institutional review board (IRB) must review and approve all non-exempt human subject research covered by an assurance. OHRP finds that the KAFBEHSP (Project Number: WIRB 20011823) is not research as defined under 45 CFR 46.102(d). In specific, this project is an investigation and screening but it is not designed to contribute to generalizable knowledge about the effects of living in the geographical distribution (plume) of potentially toxic substances. KAFBEHSP does not meet the regulatory definition of research as it lacks the stated purpose or reasonable expectation that its results would contribute to generalizable knowledge. It is by contrast limited to knowledge about the population on or near Kelly Air Force Base and the comprehension of health education needs, testing and health care referral for

clients subject to this exposure. From January 24, 2002 to April 30, 2002, SAMHD enrolled clients without IRB review; however, OHRP does not view this as non-compliance with 45 CFR 46 given the above finding that the KAFBEHSP is not research but is the delivery of public health care.

(2) It was alleged that the procedures for enrolling subjects failed to minimize the possibility of coercion or undue influence as required by HHS regulations at 45 CFR 46.116. In specific, it was alleged that the advertizement of "free door-to-door health surveys" did not mention that the surveys were research. Based upon the above finding that the KAFBEHSP is not research, OHRP finds that the requirements of 45 CFR 46.116 were not applicable to this project.

(3) It was alleged that SAMHD and the Western IRB (WIRB) failed to ensure that additional safeguards had been included to protect the rights and welfare of vulnerable subjects when research was conducted on these subjects, as required by HHS regulations at 45 CFR 46.111(b). Based on the finding that the KAFBEHSP was not research, OHRP finds that the requirements of 45 CFR 46.111(b) were not applicable to this project.

As a result of the above determinations, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter these determinations.

OHRP appreciates 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,

Paul J. Andreason, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Melanie Ritsema, Environmental Health Administrator, SAMHD
Dr. Ronald A. Gadde, Chair, WIRB Panels 1-8 & 11-12
Dr. Deborah Holtzman, Acting Deputy Associate Director for Science, CDC
Dr. Chad Heilig, Acting Manager, Human Research Protection Office, CDC
Dr. Bernard Schwetz, OHRP
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