



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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**[NOTE: REFLECTS CORRECTION IN SECTION (C) OF “CORRECTIVE ACTIONS”
SECTION TO OHRP’S DETERMINATION LETTER DATED MAY 4, 2011.]**

Gary S. Firestein, M.D.
Dean and Associate Vice Chancellor of Translational Medicine
University of California, San Diego
9500 Gilman Drive (0656)
La Jolla, CA 92093-0656

RE: Human Research Protections under Federalwide Assurance FWA - 4495

**Research Project: An Observational Study of Subjects with Primary HIV Infection:
A Study of the UCSD Acute/Early HIV Infection (AEHIV)
Clinical Studies Unit**

Principal Investigator: Susan Little, MD

Dear Dr. Firestein:

Thank you for your March 11, 2011 report in response to the Office for Human Research Protections’ (OHRP) request that the University of California, San Diego investigate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

In our February 4, 2011 letter, we made the following determination:

- (1) We determined that the use of subject names and date of births on laboratory specimens in a study where the approved protocol did not include the use of this information constituted a change to the protocol approved by the IRB in violation of HHS regulations at 45 CFR 46.103(b)(4)(iii), which require that the IRB review and approve all proposed changes in a research activity, during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects.

Given the information we reviewed, at least one subject may have suffered harm that might have been avoided if the research referenced above had been carried out as approved by the IRB. We also acknowledged that in October 2010, UCSD AntiretroViral Research Center (AVRC) changed its standard operating procedures and “negotiated submission of all samples to [a] laboratory with unique coded identifiers rather than names and [UCSD] will assume responsibility for reporting these results to the state as required by law.”

Corrective Action: We acknowledge that the following additional corrective actions were taken to ensure that researchers are aware of the institution’s revised coding SOPs, and that the IRB reviews and approves all proposed changes in a research activity, during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects:

- a. an email was sent to researchers and research staff with the link to the new policy on data coding and a reminder to adhere to the Human Research Protection Program (HRPP) policy on modifications to approved protocols;
- b. the information above was placed on the IRB website and the HRPP Director held an in-service in March to discuss these updates;
- c. the Audit Management Advisory Service (AMAS) conducted an audit of Dr. Little's active research projects to assess compliance with IRB-approved research procedures for protecting patient confidentiality. We note that the AMAS found 100% compliance with IRB approved procedures for coding data to protect subject confidentiality; and
- d. the IRB will conduct random audits of all active research protocols on which Dr. Little serves as PI for compliance with IRB-approved procedures and all aspects of managing patient confidentiality for the next 2 years.

We determine that these corrective actions adequately address our determinations and are appropriate under the UCSD FWA. At this time, there should be no need for further involvement by our office in this matter.

We appreciate 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,

Lisa Buchanan, MAOM
Division of Compliance Oversight

Dr. Firestein - University of California, San Diego

May 4, 2011

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cc:

Dr. Michael Caligiuri, Human Protections Administrator, University of California, San Diego

Dr. Mark Wallace, Chairperson, IRB 1A, University of California, San Diego

Dr. Jody Corey-Bloom, Chairperson, IRB 1B, University of California, San Diego

Dr. Patrick Patterson, Chairperson, IRB 2, University of California, San Diego

Dr. Jane Burns, Chairperson, IRB 3, University of California, San Diego

Dr. William Penny, Chairperson, IRB 4, University of California, San Diego

Ms. Judith Brooks, National Institute of Allergy and Infectious Diseases

Dr. Sherry Mills, National Institutes of Health

Mr. Joseph Ellis, National Institutes of Health