



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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February 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 December 8, 2010 report in response to our October 1, 2010 request that University of California, San Diego (UCSD) investigate allegations of noncompliance with the Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on our review, we make the following determination:

A. Determination regarding the above-referenced research.

- (1) A complainant alleged that the research referenced above failed to protect subjects' privacy and confidentiality. Specifically, the complainant alleged that UCSD "...sent out all my laboratory specimens [sic] to private laboratory with my first name, last name, DOB and SSN."

We reviewed your responses and the materials provided. We noted that the institutional review board (IRB) approved protocol states that "all laboratory specimens, evaluation forms, reports, and other records will be identified by a coded number only to maintain subject confidentiality." Per your response, the UCSD IRB states that it "...was not aware that the PI was including names to identify samples sent to outside laboratories... [and] ...approved the research...with the understanding that the PI was coding all

samples as described in her research plan.”

We determine that the use of subject names and date of births on laboratory specimens constitutes 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.

Corrective Action: We acknowledge 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.”

Required Action: Please provide a plan to ensure that researchers are aware of the institution’s revised coding SOPs, and that the IRB must 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. Also, please investigate whether similar noncompliance occurred with other studies conducted by this researcher.

Please provide us with responses to the above determination by March 11, 2011, including the requested corrective action plans. Feel free to contact me if you would like advice in developing a corrective action plan.

We appreciate the continued commitment of your institution to the protection of human research subjects.

Sincerely,

Lisa Buchanan, MAOM
Compliance Oversight Coordinator
Division of Compliance Oversight

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

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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