



Office for Human Research Protections
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February 21, 2003

Albert Carnesale, Ph.D.
Chancellor
University of California - Los Angeles
Office of the Chancellor
405 Hilgard Avenue
Los Angeles, CA 90095-1405

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1127

Research Activity: Don H. Catlin, *et al*, Detection of Norbolethone, an Anabolic Steroid Never Marketed, in Athletes' Urine, Rapid Commun. Mass Spectrom., 2002; 16: 1273-1275.

Dear Dr. Carnesale:

The Office for Human Research Protections (OHRP) has reviewed the University of California - Los Angeles' (UCLA) November 12, 2002 response to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) that were presented in OHRP's October 8, 2002 letter regarding the above-referenced publication.

The allegations involved the following:

- (1) The principal investigator failed to obtain the legally effective informed consent of subjects or their legally authorized representatives prior to conducting human subject research, as required by HHS regulations at 45 CFR 46.116.
- (2) The investigators failed to provide adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, as required by HHS regulations at 45 CFR 46.111(a)(7).

Based upon review of your report, OHRP finds that the above allegations could not be substantiated. In particular, OHRP acknowledges the following statements in UCLA's November 12, 2002 report:

- (1) "The UCLA Olympic Laboratory operates under contract with the United States Anti-Doping Agency (USADA) to provide clinical testing for drugs prohibited by the International Olympic Committee and is not a research laboratory."
- (2) "The UCLA Olympic Laboratory was provided with coded samples and was not aware of [the complainant's] name or any other personally identifiable information."
- (3) "The referenced article, however, did not constitute human subjects research as it was not a systematic investigation but rather a 'case report' on an unusual finding in a clinical laboratory of a drug test."
- (4) "Documentation provided by [the complainant] establishes that the U.S. Olympic Committee (USOC) *Olympic News*, July 10, 2002 press release publicly identified her as the athlete who tested positive for norbolethone, not the authors of the article. Dr. Catlin was unaware that the USOC would publish her name in association with the detection of norbolethone in a press release.

As a result of the above determination, 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 this determination.

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Daniel Neuman, Executive Vice Chancellor, UCLA
Dr. Judith Brookshire, Director, Office for Protection of Research Subjects, UCLA
Dr. Don Catlin, UCLA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP

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Mr. George Gasparis, OHRP

Ms. Shirley Hicks, OHRP

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Mr. Barry Bowman, OHRP