DEPARTMENT OF HEALTH & HUMAN SERVICES

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August 17, 2001

William H. Parker
Vice Chancellor for Research
155 Administration Building
University of California, Irvine
Irvine, CA 92697-3175

RE: Human Research Protections Under Multiple Project Assurance (MPA) # 1305
Research Projects: Evaluation of Pulse Oximeters

Dear Mr. Parker:

The Office for Human Research Protections (OHRP) has reviewed your July 27, 2001 report regarding the above referenced research that was submitted in response to OPRR's June 11, 2001 letter.

Based on its review, OHRP makes the following additional determinations:

(1) OHRP finds that the informed consent documents reviewed and approved by the IRB for HS #93-384 failed to adequately address the following elements required by HHS regulations at 45 CFR 46.116(a):

(a) Section 46.116(a)(1): (i) the expected duration of the subject's participation; and (ii) a description of the procedures to be followed. In particular, the protocol and publications resulting from this research described procedures which were not mentioned in the informed consent document.

(b) Section 46.116(a)(2): A description of any reasonably foreseeable risks and discomforts. The informed consent document did not mention the following: (i) consequences of occurrence of any of the risks nor their treatment; and (ii) possible adverse reaction to lidocaine.

(2) HHS regulations at 45 CFR 46.116 require that the information that is given to subjects must be in language understandable to the subject. OHRP finds that the informed consent document approved by the IRB for HS #93-384 included complex language that would not be understandable to all subjects.

(3) HHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. OHRP finds that continuing review for HS #94-215 occurred less often than annually.

Corrective Actions: OHRP acknowledges that these studies have ended and that since review of this research was conducted, additional IRB staff have been hired and additional training and education of staff and investigators have been implemented. In addition, the faculty and staff of the department at which the above-referenced research was conducted have been directed to obtain specific training, including documentation of informed consent and recruitment methods. OHRP acknowledges UCI's current practices include special attention to review of informed consent documents, specifying the category that justifies expedited review, and that upon expiration of IRB approval, the investigator is notified in writing to halt accrual of new subjects and asked to either apply for continuing review immediately or submit a final report. OHRP finds that the corrective actions taken by UCI adequately address OHRP's findings and concerns regarding the above referenced research project and are appropriate under the UCI Multiple Project Assurance. As a result, OHRP is closing this case and 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,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Dr. Ralph J. Cicerone, Chancellor, UCI
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