DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8132
FAX: 240-453-6909
E-mail:Kristina.borror@hhs.gov

March 30, 2009

Bertram Lubin, M.D.
President
Children's Hospital Oakland Research Institute
5700 Martin Luther King Jr. Way
Oakland, CA 94609

RE: Human Research Subject Protections under Federalwide Assurance (FWA) 0094

Dear Dr. Lubin:

Thank you for your March 20, 2009 report in response to our February 19, 2009 request that Children's Hospital Oakland Research Institute, California (CHORI) respond to determinations, questions and concerns arising from our August 5–7, 2008 on-site evaluation regarding compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

Determinations made in our February 19, 2009 letter regarding your institution's system for protecting human subjects

(1) We determined that certain informed consent documents reviewed and approved by the CH institutional review board (IRB) failed to include or adequately address numerous elements required by HHS regulations at 45 CFR 46.116(a). Moreover, there was no evidence demonstrating that the IRB approved any waiver or alteration of the informed consent requirements for the above referenced protocols in accordance with 45 CFR 46.116(d).

Corrective Action: We acknowledge that a reviewer checklist for informed consent is provided to each IRB member along with meeting materials and the primary reviewer must complete the checklist and other members are encouraged to do so. We acknowledge your statement that no informed consent documents lacking any of the required elements will be approved without a waiver or alteration of the informed consent requirements in accordance with the regulations. We determine that these corrective actions adequately addresses our determination of noncompliance.

(2) We determined that the CHORI IRB was inconsistent on occasion when it made the findings required for approval of research involving children as required by HHS regulations at 45 CFR 46.405.

Corrective Action: We acknowledge that the CH IRB has developed a handout for IRB members to assist them with definitions and requirements to make the necessary findings for research involving children. We determine that this corrective action adequately addresses our determination of noncompliance.

(3) We determine that your March 20, 2009 response adequately addresses concern C presented in our February 19, 2009 letter.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

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,

Kristina C. Borror, Ph.D.
Director, Division of Compliance Oversight

Cc: Denyse Pettersson, CIM, CIP
John R. Waterson, M.D., Ph.D.
Commissioner, Food and Drug Administration
Dr. Joanne Less, Food and Drug Administration
Dr. Sherry Mills, National Institutes of Health
Mr. Joseph Ellis, National Institutes of Health