DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 7, 2004

Richard A. Molteni, M.D.
Medical Director
Children's Hospital and Regional Medical Center
Hospital Administration CH-01
4800 Sand Point Way, N.E.
Seattle, WA 98105

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1214 and Federalwide Assurance (FWA) 00002443

Research Activity: **Munchausen Syndrome by Proxy Research**
Principal Investigator: **Dr. Kenneth Feldman**

Dear Dr. Molteni:

The Office for Human Research Protections (OHRP) has reviewed Children's Hospital and Regional Medical Center's (CHRMC) November 14, 2002 letter in response to OHRP's October 8, 2002 letter regarding the above-referenced research. Based on the documents provided in your report, OHRP makes the following determinations regarding the above-referenced research:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b) and 46.109(a) require that the institutional review board (IRB) must review and approve all non-exempt human subject research covered by an assurance. OHRP finds that certain human subject research involving the collection of information in a research database by the above-named investigator was conducted without IRB review.

(2) HHS regulations at 45 CFR 46.116 state that, except as provided elsewhere in the regulations, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. OHRP finds that the investigator initiated the human subject research noted in item (1), above, without meeting this requirement.

OHRP notes that CHRMC has taken the following additional corrective actions:

> (1) CHRMC officials have met with and educated the principal investigator regarding the use of confidential medical records and requirements for the protection of human subjects.
>
> (2) CHRMC officials provided staff in all departments with an IRB information sheet regarding retrospective record review research.
>
> (3) CHRMC has held two training sessions for its staff to discuss the IRB requirements for use of existing data and specimens.
>
> (4) CHRMC established a committee to develop a hospital policy regarding tissue and data banking, as well as the establishment of personal databases which contain private identifiable information.

OHRP finds that the corrective actions noted above adequately address the findings of noncompliance noted in items (1) and (2), above and are appropriate under the CHRMC FWA. As a result of this 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.

At this time, OHRP has the following additional guidance:

> 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. Where the convened IRB specifies conditions for approval of a protocol that are to be verified as being satisfied by the IRB Chair or another IRB member designated by the Chair, continuing review must occur no more than one year after the date the protocol was reviewed by the convened IRB, not on the anniversary of the date the IRB Chair or his or her designee verifies that IRB-specified conditions for approval have been satisfied.

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: Ms. Elizabeth Trias, Manager, Institutional Review Board, CHRMC
Dr. Douglas Diekema, IRB Chair, CHRMC
Dr. Kenneth Feldman, CHRMC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Ms. Jan Walden, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Melinda Hill, OHRP