DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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March 3, 2008

Peter J. Deckers, M.D.
Executive Vice President for Heath Affairs
University of Connecticut Health Center
263 Farmington Avenue
Farmington, CT 06030-3826

RE: Human Research Subject Protections Under Federalwide Assurance FWA-6064

Research Project:	Effects of Aripiprazole on Subjective and Physiological Responses to Alcohol
Principal Investigator:	Henry Kranzler, M.D.
Project Number:	GCRC #536 (MO1 RR06192); IRB 04-108

Research Project:	Targeted Naltrexone for Problem Drinkers
Principal Investigator:	Henry Kranzler, M.D.
Project Number:	GCRC #495; IRB 03-107

Research Project:	Sertraline Pharmacotherapy for Alcoholism Subtypes
Principal Investigator:	Henry Kranzler, M.D.
Project Number:	GCRC #531; IRB 03-225

Dear Dr. Deckers:

Thank you for your January 28, 2008 report in response to our December 17, 2007 letter regarding research conducted under the above-referenced research projects.

I. In our December 17, 2007 letter, we made the following determinations:

A. We determined that Dr. Kranzler conducted non-exempt human subjects research without prior Institutional Review Board (IRB) review and approval when he created a recruitment database containing identifiable private information, i.e., names, contact information and health information, from IRB #04-108 phone excludes.

B. We determined that Dr. Kranzler conducted non-exempt human subjects research, i.e., establishment of a blood bank repository containing biological specimens with identifiable private information, without prior IRB review and approval.

Corrective Action: Given the potential systemic nature of these findings, we asked the University of Connecticut Health Center (UCHC) to provide a list of actions the UCHC IRB has taken/will take regarding other investigators who may have engaged in non-exempt human subjects research, i.e., created a human subjects participant registry containing identifiable private information and/or created a research specimen repository containing identifiable private information, without prior IRB review and approval. We acknowledge that the UCHC IRB has taken the following responsive actions:

1. Issued a broadcast message to the UCHC community which reiterated the policy regarding the need for a research registry/repository to be approved by the IRB before adding subject information to it and that subjects must provide consent for participation in the registry/repository. The message also instructed all investigators that if they had any identifiable samples from previous studies that the material must be stripped of identifiers or discarded appropriately and 2) that if investigators relied on the Health Insurance Portability and Accountability Act (HIPAA) template for permission to maintain personally identifiable health information for purposes of recruitment, that all personally identifiable health information had to be removed and only general mailing information could be maintained.
2. Revised the HIPAA template for research authorization to reflect that only name and address may be used to establish a general mailing list. The research community was informed of this change via the same broadcast message referenced above and instructed to submit the revised form.
3. Notified all personnel involved with human subject research of the above referenced actions via a quarterly newsletter which is published by the IRB office.
4. Issued a second broadcast message that reiterated the information contained in action item (1) above.
5. Added language to the UCHC informed consent form template which provides guidance to reflect that separate approval/consent/authorization are required to add information to a registry/repository. This new informed consent form language will be included in the next Human Subjects Protection Office (HSPO) quarterly newsletter.
6. Instructed IRB Chairs and support staff to screen informed consent forms for issues regarding sample collection and storage and to instruct investigators to take necessary corrective actions if needed.
7. Requested Research Compliance Monitors to check for compliance with the corrective actions issued by the HSPO/IRB during audits and to continue to educate investigators about the need to seek prior IRB review and approval for a registry/repository and the need for specific subject consent and authorization in order to add identifiable private information to a registry/repository.

These corrective actions satisfactorily address our prior determinations, and are appropriate under the terms of the UCHC FWA

II. Questions and Concerns

A. [Redacted]

OHRP acknowledges all of the remaining January 28, 2008 UCHC responses that are not specifically addressed above.

Please submit your response to this outstanding question and concern so that we receive it no later than April 4, 2008. If during your review you identify additional areas of noncompliance with Department of Health and Human Services regulations for the protection of human subjects,

please provide corrective action plans that have been or will be implemented to address the noncompliance.

We appreciate your institution's continued commitment to the protection of human research subjects. Please contact me if you should have any questions regarding this matter.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator

cc: Dr. Richard H. Simon, Director, Human Subjects Protection Office, UCHC
Ms. Judi Kulko, IRB chairperson, UCHC IRB #1
Dr. Ronald M. Kadden, IRB chairperson, UCHC IRB #2
Dr. Mahlon Hale, IRB chairperson, UCHC IRB#1 - Panel 03
Dr. Nancy R. Rodrigues, IRB chairperson, University of Connecticut, Storrs IRB #1
Dr. Amira Pierucci-Lagha, UCHC
Dr. Henry Kranzler, UCHC
Ms. Sherry Mills, NIH Office of Extramural Research
Mr. Joe Ellis, NIH, Office of Extramural Research
Dr. Andrew C. von Eschenbach, Commissioner, FDA
Dr. Joanne R. Less, FDA