DEPARTMENT OF HEALTH & HUMAN SERVICES

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OFFICE OF PUBLIC HEALTH AND SCIENCE

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March 30, 2001

Eric Gislason, Ph.D.
Interim Vice Chancellor for Research
Office of the Vice Chancellor for Research (MC 672)
University of Illinois at Chicago
310 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1095

(1) Research Activity: Induction of a dissociative state in a psychiatric patient and evaluation with radiologic brain imaging for research purposes Investigator: Dr. Thomas Jobe

(2) Research Activity: Assessment of the effectiveness of respiridone for the treatment of patients with psychosis due to medical conditions and measurement of steady-state trough levels of respiridone and 9-hydroxyrisperidone concentrations in such patients. Investigators: Dr. Kevin Furmaga, Dr. Ovidio DeLeon, Dr. Shobha Sinha, Dr. Thomas Jobe and Dr. Moises Gaviria

(3) Research Activity: College of Nursing research project. Investigator: Dr. Rosemary White-Traut

(4) Research activity: Research involving an investigational device, surgical glue, for neurosurgery procedures. Investigator: Dr. Gerard Debrun

(5) Research activity: Research involving ultra rapid opiate detoxification (UROD). Investigator: Dr. Joseph Flaherty

(6) Research Activity: Multiple research projects conducted by Department of Psychiatry investigators

Dear Dr. Gislason:

The Office for Human Research Protections (OHRP) has reviewed your report of February 6, 2001, regarding the above referenced research projects.

OHRP acknowledges that the Human Subject Investigation Committee (HSIC) of the University of Illinois at Chicago (UIC) conducted a comprehensive review of the above referenced research projects and found noncompliance with regulations for protection of human subjects with respect to all six research activities. In particular, the HSIC found that in the case of five research activities (i) the responsible investigators failed to obtain Institutional Review Board (IRB) approval for the research, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.109(a), and (ii) legally effective informed consent was not obtained for all subjects, as required by HHS regulations at 45 CFR 46.116. In the sixth case, involving research activities of Dr. Rosemary White-Trout, the HSIC found that the investigator failed to obtain IRB approval for amendments to informed consent documentation prior to initiation of such changes, as required by HHS regulations at 45 CFR 46.103(b)(4)(iii).

OHRP recommends that the UIC IRB consider whether human subjects involved in the five research activities for which the HSIC found that legally effective informed consent was not obtained, should be contacted and informed of their heretofore unknown participation in the research.

OHRP notes that the Interim Vice Chancellor for Research (VCR) embraced the conclusions of the HSIC, and determined that the noncompliance with HHS human subject protection requirements was caused by the following institutional problems:

(1) a pervasive disrespect for the primacy of human subject protection by former senior administrators at UIC, which undermined the authority and autonomy of the IRB and enabled investigators and department administrators (notably the Medical College Executive Medical Committee) to identify research interventions as treatment options and thereby circumvent unfavorable IRB decisions;

(2) inadequate resources dedicated to human subject protection at UIC (manpower, space, information system technology, and budget); and

(3) insufficient education for all parties involved research activities at UIC (administration, investigators, research staff, students, IRB members, and other UIC employees) about the ethical and regulatory requirements for human subject protection.

OHRP previously found that UIC has initiated corrective actions to address these deficiencies in UIC's system for human subject protection. See OHRP letter of July 18, 2000. Specifically, OHRP notes the following:

(1) UIC has established an extensive initial and continuing education program for administration, investigators, research staff, students, IRB members, and OPRS staff, on the ethical principles and regulatory requirements for human subject protection.

(2) UIC is providing sufficient financial resources to accomplish the review and oversight functions described in the HHS regulations, including twelve full-time academic staff and four full-time civil service staff to serve three IRBs. A state of the art, comprehensive regulatory compliance information system for managing UIC's human subject research protocol database is in the final stages of development.

(3) UIC appears committed to ensuring the autonomy of the IRB and its administrative apparatus, the Office for the Protection of Research Subjects (OPRS), and to preventing future circumvention of IRB decisions by investigators or department personnel.

(a) Policies are under development to establish appropriate roles for the IRB and departmental entities such as the Medical College Executive Medical Committee and the Departmental Review Committees, and to clarify criteria for distinguishing standard of care interventions from research procedures so that subjects participating in research are adequately informed and protected.

(b) UIC Medical Center treatment consent forms are being revised to delete any reference to research, so that individuals who consider participating in research will receive appropriate informed consent documentation.

Anticipating full implementation of the corrective actions described above, OHRP is closing its compliance oversight investigation of this matter and there should be no need for further OHRP involvement. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of UIC to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.
Division of Compliance Oversight

cc: Dr. Greg Koski, OHRP
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