DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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December 21, 2001

Jonathan R. Cole
Provost and Dean of Faculties
Columbia University in the City of New York
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535 West 116th Street
New York, New York 10027

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1309

Research Project: Research investigating how restaurants handle food-poisoning complaints
Principal Investigator: Professor Frank Flynn

Dear Dr. Cole:

The Office for Human Research Protections (OHRP) has reviewed your November 28, 2001 report regarding indications of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects involving the above-referenced research.

Based upon its review, OHRP makes the following determinations regarding the above-referenced research:

(1) HHS regulations at 45 CFR 46.103(b) and 46.109(a) require that the Columbia University Institutional Review Board (IRB) review and approve all non-exempt human subject research covered by MPA M-1309. OHRP finds that the research was conducted without IRB review.

(2) HHS regulations at 45 CFR 45.116 stipulate 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 subjects or the subject's legally authorized representative. OHRP finds that the investigator initiated human subject research without meeting this requirement.

Corrective Actions: OHRP further finds that the following corrective actions taken by Columbia University (CU) adequately address the above findings:

(a) The CU IRB promptly directed the principal investigator to halt the above-referenced research.

(b) The CU IRB promptly suspended any other human subjects research being conducted by the principal investigator until he satisfactorily completed a full-day human subjects protection training program course and test.

(c) The principal investigator has sent out letters of apology to the staff at restaurants involved in the research.

(d) All full-time faculty of the CU Business School were contacted and advised to take the National Institutes of Health's (NIH's) computer based training course, "Human Participant Protections Education for Research Teams."

(e) The Vice Dean of the CU Business School has constituted a new committee to recommend procedures to ensure Business School faculty compliance with IRB requirements.

(f) CU has expanded Human Subject Research Training aimed at all faculty and researchers.

(g) CU has revised the on-line version of the CU Faculty Handbook to include a detailed description of what constitutes human subjects research and the procedures for conducting such research at CU.

(h) CU plans to recruit additional IRB members to serve as representatives for CU students and for schools that are not already represented on the IRB.

(i) CU is developing a mandatory computer-based education training program for the social and behavioral sciences that will replace the current mandatory computer-based training provided by NIH.

(j) CU plans to begin auditing, on a random basis, human subjects research protocols

and training programs.

As a result of the above corrective actions, 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 provides the following additional guidance to CU regarding its written IRB policies and procedures:

(1) The written IRB policies and procedures should be expanded to provide the operational details for each of the following procedures required by HHS regulations at 45 CFR 46.103(b)(4) and (5):

(a) The procedures which the IRB follows for conducting its initial review of research.

(b) The procedures which the IRB follows for conducting its continuing review of research.

(c) The procedures which the IRB follows for reporting its findings and actions to investigators and the institution.

(d) The procedures which the IRB follows for determining which projects require review more often than annually.

(e) The procedures which the IRB follows for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

(f) The procedures which the IRB follows for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(g) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

(2) Please note that the CU MPA is not a sufficient substitute for detailed written IRB policies and procedures.

(3) Please see the enclosed document, "Guidance for Formulating Written IRB Policies and Procedures," for points to consider in revising CU's written IRB policies and procedures.

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,

Michael A. Carome, M.D.
Director
Division of Compliance Oversight

Enclosure: Guidance for Formulating Written IRB Policies and Procedures

cc: Professor Andre Ivanoff, Chair, Morningside IRB, CU
Ms. Alison Dewhurst, Administrator, Morningside IRB, CU
Professor Frank Flynn, CU
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP