DEPARTMENT OF HEALTH & HUMAN SERVICES

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January 31, 2001

Peter K Bridson, Ph.D.
Vice Provost for Research
The University of Memphis
308 Administration Building
Memphis, TN 38152

**RE: Multiple Project Assurance (MPA) M-1485**

Dear Dr. Bridson:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed the March 23, 2000 report from the University of Memphis (UM), that was submitted in response to OPRR's February 18, 2000 letter.

Based upon its review, OHRP has determined that UM has implemented all actions required by OPRR, and adequately addressed all concerns raised by OPRR in its February 18, 2000 letter. In particular, OHRP notes the following:

(1) The UM suspended all Federally supported research projects that were approved by the UM Institutional Review Board (IRB) without the quorum requirements stipulated by Department of Health and Human Services (HHS) regulations at 45 CFR 46.108 being satisfied. Furthermore, these projects were subsequently reviewed and approved by the UM IRB at an appropriately convened meeting on February 21, 2000.

OHRP notes that the current IRB chair, Dr. Corinna Ethington, is considered to have her primary concerns in a non-scientific area. However, Dr. Ethington has a doctorate degree and conducts research in educational research, a scientific area.

Therefore, she should not be considered to be a member whose primary concern is in a nonscientific area. However, Ms. Irma Russell, who is a lawyer and a member of the IRB, can be considered to have her primary concern in a nonscientific area. As Ms. Russell also attended the February 21, 2000 IRB meeting, the meeting can be considered to be appropriately convened.

(2) The UM has developed expanded written IRB Policies and Procedures that adequately describe the operational details for each IRB and institutional activity in accordance with the requirements at HHS regulations at 45 CFR 46.103(b)(4) and (5).

As a result, OHRP has determined that there should be no need for further involvement of OHRP in the above referenced matter. Of course, OHRP must be notified should new information be identified which might alter these determinations.

At this time OHRP would like to provide the following additional guidance:

(3) HHS regulations at 45 CFR 46.304 require modification of the IRB membership for review of research involving prisoners. In specific, at least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. Since the prisoner representative was a non-voting member, the IRB failed to meet this requirement when reviewing research project H9923, "A Standardized Empirical Investigation of Information Processing Deficits in Schizophrenia."

OHRP notes that the UM plans to develop a separate IRB that includes a prisoner advocate as a voting member to review research involving prisoners. In choosing an appropriate prisoner representative, the suitability of such candidates should be concordant with OHRP Guidance on Approving Research Involving Prisoners (see OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prison.htm). In addition, HHS regulations at 45 CFR 46.305-306 require specific findings on the part of the IRB for approval of research involving prisoners. OHRP strongly recommends that these findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

(4) OHRP also notes that section 3.3 of the revised UM Policy and Procedures states that "full board review" by the UM IRB is required for any research that "involves more than minimal risk." This section should be expanded to indicate that research involving no more than minimal risk and activities not covered by the list of categories at 63 FR 60364 also requires full board review.

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,

Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Greg Koski, OHRP
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