DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY
OFFICE OF PUBLIC HEALTH AND SCIENCE

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March 28, 2001

Kern Wildenthal, M.D., Ph.D.,
President, The University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, TX 75235

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1304**
**Research Project: Study of the Gulf War Syndrome: Multidisciplinary Pathophysiologic Studies of Neurotoxic Gulf War-Related Syndromes Leading to Diagnosis and Treatment**
**Principal Investigator: Robert W. Haley, M.D., Director, Epidemiology Division, UTSWMC**

Dear Dr. Wildenthal:

The Office for Human Research Protections (OHRP) has reviewed your letter of February 23, 2001, regarding the protection of human research subjects at the University of Texas Southwestern Medical Center (UTSWMC).

OHRP has determined that UTSWMC has adequately responded to all required corrective actions and concerns set forth in OHRP's letter of January 23, 2001. Specifically, OHRP finds the following:

(1) UTSWMC has developed an informed consent template form for researchers which contains each of the elements of informed consent required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(a). Furthermore, UTSWMC has revised its institutional review board (IRB) Policies and Procedures to embody the requirements of 45 CFR 46.116(a), and implemented a procedure requiring IRB review of all submitted protocols specifically for inclusion of these requirements.

(2) UTSWMC suspended federally supported research studies not eligible for expedited review which had received initial IRB approval prior to January 23, 2000. UTSWMC also

implemented procedures for providing substantive and meaningful continuing review by the convened IRB. Under UTSWMC' s revised continuing review procedures, for protocols undergoing continuing review by the convened IRB, each IRB member receives a protocol summary, updated informed consent documentation, and any relevant information regarding adverse events, recent scientific findings, and study amendments. Separate deliberations and votes are held for each protocol undergoing continuing review, and the IRB minutes document such discussions and actions.

(3) The UTSWMC IRB has revised its procedures for recording the minutes of meetings, to ensure that the minutes comply with the requirements of HHS regulations at 45 CFR 46.115(a)(2). UTSWMC IRB minutes now describe the controverted issues discussed, and identify the members present for each protocol including the number voting for, against, or abstaining from each action taken by the IRB.

(4) UTSWMC has incorporated into its IRB Policies and Procedures the guidance provided by OHRP regarding (i) requirements for waiver of informed consent and for waiver of documentation of informed consent, and (ii) procedures for determining appropriate continuing review periods, and for ensuring prompt reporting of unanticipated problems involving research risks and noncompliance with human subject protection requirements.

As a result of the above determinations, 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 these determinations.

OHRP appreciates UTSWMC's continued commitment to the protection of human research subjects. Should you have any questions, feel free to contact me.

Sincerely,

Carol J. Weil, JD
Division of Compliance Oversight

cc: Dr. Perrie M. Adams, UTSWMC
Dr. Robert Haley, UTSWMC
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Clifford C. Scharke, OHRP
Dr. Doug C. Forcino, Department of Defense

Mr. Barry Bowman, OHRP
Dr. John Mather, ORCA, Department of Veterans Affairs
Commissioner, FDA
Dr. David Lepay, FDA
Dr. John Feussner, Department of Veterans Affairs