



OFFICE OF THE SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

FEB 17 1994

MEMORANDUM TO DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: Protection of Human Subjects in Research

On August 11, 1991, the Federal Common Policy for the Protection of Human Subjects in Research was adopted by the Department of Defense (DoD) and published in Title 32, Code of Federal Regulations, Part 219. Subsequently, Policy Guidance for implementation of the Human Subjects Regulations was issued jointly on June 10, 1993 by the Assistant Secretary of Defense (Health Affairs) and the Office of the Director, Defense Research and Engineering to the Assistant Secretaries of the Military Departments having cognizance for research, development, testing, and acquisition.

It has been brought to our attention that at least one Defense Agency has recently initiated a program in medical technology. To ensure that all Department of Defense Agencies are in compliance with current human use regulations, it is requested that each Director indicate whether his Agency conducts or provides funding support for intramural or extramural research which involves human subject participation. If an Agency does conduct or support human subjects research the required administrative package will be provided to ensure Agency compliance with the above Federal Regulation. For clarity, research is defined as a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Human subjects is defined as a living individual about whom an investigator (professional or student) conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information regarding the individual used for research purposes.

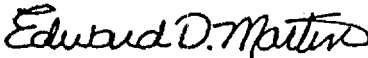
Directors are requested to provide the status of Agency participation in the conduct or support of intramural or extramural human subject research by March 4, 1994 to

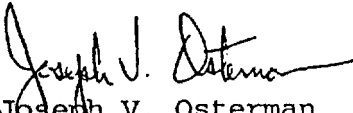
Director, Environmental and Life Sciences
Office of the Director, Defense Research and Engineering
Pentagon Room 3D129
Washington, D.C., 20301-3030

Negative responses are required.

NO REFERRAL REQUIRED

My point of contact for this action is Captain John F. Jemionek, MSC, USN, who may be contacted at (703) 697-1494. Your assistance in ensuring total DoD compliance with Federal Regulation in the area of human subject protection in research is appreciated.


Edward D. Martin, M.D.
Acting Assistant Secretary
of Defense (Health Affairs)


Joseph V. Osterman
Director, Environmental
and Life Sciences