THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

JUN 27 2003

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Designation of a Single Human Use Review Board for the Review of Blood Donor Screening for West Nile Virus Using an Investigational Test

The 2002 WNV epidemic involved the first documented cases of WNV transmission through organ transplantation and blood transfusion. In May 2003, the FDA published guidance directing the industry to test blood for WNV as soon as a test becomes available. On June 2, 2003, the Deputy Assistant Secretary of Defense, Force Health Protection and Readiness, issued a policy letter instructing the Services to implement nucleic acid testing (NAT) for WNV under investigational procedures. The two major blood collection agencies in the United States, the American Red Cross and America's Blood Centers, plan to test for West Nile Virus using a newly developed IND test kit on the first of July 2003.

Because the use of an IND test kit to screen DoD volunteer blood donors requires IRB approval and to assure consistency throughout DoD, this policy memorandum officially designates the Army Surgeons General's Human Subjects Research Review Board as the single Institutional Review Board (IRB) to review an Investigational New Drug (IND) protocol for the use of a nucleic acid test for West Nile Virus (WNV). The test will be used to screen volunteer blood donors presenting for blood donation at DoD operated blood collection centers.

DoD Directive 6000.12, "Health Services Operations and Readiness," April 29, 1996, requires that the Armed Services Blood Program operate as a single, integrated blood products system, and do so under the Executive Agency of the Secretary of the Army, through the Surgeon General of the Army. Accordingly, the Surgeon General of the Army shall develop and coordinate an IND protocol for the use of the West Nile Virus NAT. The protocol shall comply with FDA's IND regulations (21 CFR Part 312). Please provide all possible support and assistance for this important initiative.

The point of contact for this action is CAPT (S) Brenda Bartley, 703-681-1736, Brenda.bartley@otsg.amedd.army.mil.

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cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

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