



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

FEB 3 2003

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 Protocols as "Contingency Investigational New Drug Protocols for Force Health Protection"

The increasing threat of the use of weapons of mass destruction necessitates the implementation of investigational new drug (IND) protocols for force health protection. DoD Directive (DoDD) 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000, establishes policy and assigns responsibility for use of INDs for force health protection in the Department of Defense.

This policy memorandum officially designates the following U.S. Army Surgeon General IND protocols as "Contingency IND Protocols for Force Health Protection" and thus subject to the provisions of DoDD 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000.

- a. "Contingency Protocol for the Administration of Vaccinia Immune Globulin – IM (Human) to Subjects who Experience Complications Resulting from Vaccination with Vaccinia Virus," IND 8429, version 13, dated August 2, 2002.
- b. "Department of Defense Contingency Protocol for Emergency Use of Cidofovir (VISTIDE) as a Treatment for Smallpox," IND 65480, dated July 5, 2002.
- c. "Department of Defense Protocol for the Use of Cidofovir (VISTIDE) as a Treatment for Adverse Reactions Associated with Vaccinia Virus Vaccination," IND (pending submission to FDA).
- d. "Contingency Protocol for Vaccination with Pentavalent Botulinum Toxoid to Protect Against Botulinum Toxin Toxicity," IND 3723, version 6.1, dated June 10, 2002.
- e. "Emergency Use Protocol for Botulinum Antitoxins," IND 10621, version 19, dated August 6, 2002.
- f. "Contingency Protocol for Anthrax Vaccination to Protect Against *Bacillus anthracis* Spores," IND 10081, version 9, dated July 8, 2002 (to include Appendix K, Pediatric Addendum).

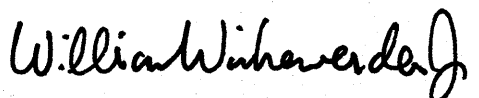
The Secretary of the Army, as Executive Agent, develops Contingency IND protocols for force health protection. These protocols are subject to approval by the Army Surgeon General's

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Institutional Review Board (IRB) known as the Human Subjects Research Review Board (HSRRB). DoDD 6200.2 section 4.5 states, "The Army Human Subjects Research Review Board (HSRRB), under the Surgeon General of the Army, is designated as the IRB responsible for purposes of IRB activities under this Directive."

It is vitally important that we have coherence and consistency in the implementation of IND protocols; therefore, the Army Surgeon General's HSRRB will be the only IRB of record for these protocols. Local Army, Navy, Air Force and Marine Clinical Investigation Program (CIP) IRBs may individually review the Contingency IND Protocols for force health protection, but may not modify them. Every effort will be made to keep regional CIP IRBs fully informed of the status of these protocols (for information only).

Request you immediately implement the provisions of DoDD 6200.2 with regard to the above-listed Contingency IND Protocols for force health protection. My POC for this action is Salvatore Cirone, Program Director for Health Science Policy. He can be contacted at (703) 575-2679 or at Salvatore.Cirone@ha.osd.mil.



William Winkenwerder, Jr., MD

cc:

Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Commander, USAMRMC