



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

OCT 25 2004

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Update to Health Affairs Policy 03-003, Designation of Protocols as
"Contingency Investigational New Drug Protocols for Force Health
Protection"

REFERENCE: HA Policy 03-003, Designation of Protocols as Contingency
Investigational New Drug Protocols for Force Health Protection,
February 3, 2003

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

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

To facilitate coherence and consistency in the implementation of IND protocols, 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 IRBs may individually review the contingency IND protocols for force health protection, but may not modify them. Participating investigators need to communicate with their chains of command and their military treatment facility IRBs regarding their involvement in contingency protocols in accordance with local institutional requirements.

The Army Surgeon General, on behalf of the Secretary of the Army, as Executive Agent per DoDD 6200.2, will post a list of current contingency IND protocols and will update as new IND protocols become available. This list is available at <https://fhp.osd.mil/portal/ind/index.jsp>. New clinical site requests for use of the

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contingency force health protection protocols must be submitted from the respective Service Surgeons General to my office.

My point of contact for this action is Salvatore Cirone, Program Director for Health Science Policy. He can be contacted at (703) 575-2670 or at Salvatore.Cirone@ha.osd.mil.

A handwritten signature in black ink that reads "William Winkenwerder, Jr." with a stylized flourish at the end.

William Winkenwerder, Jr., MD

cc:

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