DEPARTMENT OF THE ARMY
HEADQUARTERS, U. S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
AND FORT SAM HOUSTON
2250 STANLEY ROAD
FORT SAM HOUSTON, TEXAS 78234-6100

REPLY TO
ATTENTION OF

MCCS-GCI (40-38a)

13 December 2002

MEMORANDUM THRU Commander, MEDCEN, ATTN: DCCS

FOR Commander, MEDCEN, ATTN: Chief, Department of Clinical Investigation

SUBJECT: Clinical Investigation Program (CIP) Policy IND Protocols for Force Health Protection

1. The worsening threat of the use of weapons of mass destruction has forced DoD to implement investigational new drug (IND) protocols for force health protection, e.g., VIG and cidofovir for serious smallpox vaccination complications. U.S. Army regional CIP IRBs are generally responsible for IND studies (AR 40-38), but DODD 6200.2, *Use of Investigational New Drugs for Force Health Protection*, 1 August 2000, 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." AR 70-25, OTSG Regulation 15-2, and HSRRB Policy Memorandum 2002-07 also clearly specify that the HSRRB can act as an IRB on behalf of TSG.

2. Protocol coherence, consistency, and efficient implementation imply that it is unreasonable for CIP IRBs to review and approve the IND protocols for force health protection. Therefore, the HSRRB will be the only IRB of record for these protocols. However, every effort will be made to keep regional CIP IRBs fully informed of the status of these protocols (for information only).

3. Questions may be referred to COL Lamiell or LTC Martin at (210) 221-2511 (DSN 471-2511), or to HSRRB Acting Chairperson LTC Brosch at (301) 619-2165 (DSN 343-2165).

James M. Lamiell

JAMES M. LAMIELL
COL, MC
Chief, Clinical Investigation Regulatory Office