



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

S: 13 May 2005

DASG-ZH

4 May 2005

MEMORANDUM FOR Director, Health Policy and Services

SUBJECT: Approval of DoD Assurances of Compliance for the Protection Of Human Research Subjects in U.S. Army Conducted, Supported, or Contracted Human Subjects Research

1. Approval of DoD Assurances of Compliance for the protection of human research subjects in U.S. Army conducted, supported, or contracted human subjects research requires an established process.
2. The Assistant Surgeon General for Force Projection (ASG-FP) is assigned, effective upon acceptance of the U.S. Army Human Research Subjects Protection Management Plan by the Director Defense Research and Engineering, as the approval authority for Assurances of Compliance submitted by the US Army and non-Army institutional entities proposing to engage in Army supported or conducted human subjects research. These Assurances must be approved by the ASG-FP prior to accrual of human subjects in such research by the institution filing such an Assurance.
3. The U.S. Army Medical Research and Materiel Command Office of Research Protections (ORP) and the Clinical Investigation Regulatory Office (CIRO) of the US Army Medical Department Center and School serve as the portals through which Assurances are processed and will negotiate the terms of the Assurance with institutions requesting approval.
4. Completed Assurances will be forwarded through the Director, Health Policy and Services (HP&S) to the ASG-FP for review for compliance with human subjects protection requirements and approval. HP&S will be responsible for providing recommendations based on clinical review of proposed Assurances of Compliance submitted and advise ASG-FP accordingly.
5. My point of contact is COL Paul E. Gause, Senior Medical Staff Officer, Health Policy and Services Directorate, Office of The Surgeon General (703-681- 2707).

A handwritten signature in blue ink, appearing to read "Philip Volpe".

PHILIP VOLPE
COL, MC
ASG-FP