



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

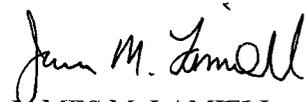
18 August 2004

MEMORANDUM FOR DEPARTMENTS OF CLINICAL INVESTIGATION

SUBJECT: Reporting of Unexpected Adverse Events

Reference: AR 40-38, para 2-10c(5) &(6)
AR 40-7, para 4-11

1. This policy describes the unexpected adverse event reporting requirements for the Army CIP.
2. Definitions:
 - a. Unexpected adverse event – any adverse experience not previously identified in nature, severity, or frequency in the protocol or investigator brochure.
 - b. Serious unexpected adverse event – any adverse experience that is fatal, life threatening, permanently disabling, require inpatient hospitalization, or result in congenital anomalies, cancer, or overdose.
3. Principal investigators are to promptly notify the approving official, through the medical monitor and the HUC/IRB, of unexpected adverse events associated with a clinical investigation protocol.
4. Principal investigators are to report serious unexpected adverse events involving the use of investigational drugs or devices to the sponsor or the FDA in accordance with AR 40-7.
5. Serious unexpected adverse events that are determined by the medical monitor to be possibly caused by the subject's participation in the clinical investigation protocol are to be reported by telephone NLT the next duty day to CIRO (210-221-2511). A written report is to follow the initial telephone call within 3 working days.
6. CIRO is committed to foster and support AMEDD CIP research. Questions may be referred to COL Lamiell or COL Martin at (210) 221-2511 (DSN 471 -2511).


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