DEPARTMENT OF THE ARMY
HEADQUARTERS, U. S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
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REPLY TO
ATTENTION OF

MCCS-GCI (40-38a)

28 March 2003

MEMORANDUM FOR Departments Of Clinical Investigation

SUBJECT: HIPAA (Health Insurance Portability and Accountability Act) Clinical Research Guidance

1. To assist with HIPAA implementation (described in 45 CFR 160, 45 CFR 164, and DoD 6025.LL-R, dated 15 October 2002), some of the relevant issues are addressed for consistency throughout the Clinical Investigation Program (CIP).

a. All fixed MTFs conducting CIP human medical research studies as described in AR 40-38 are HIPAA covered entities (DoD 6025.LL-R, DL1.1.3).

b. The use of protected health information (PHI, see 45 CFR 164.501) in CIP research studies requires individual subject authorization (DoD 6025.LL-R, C5.3) after the HIPAA implementation date (14 April 2003).

c. All greater than minimal risk CIP human medical research studies require an informed consent document (ICD) that is signed by each participating subject. These studies also require a signed HIPAA authorization.

d. Some minimal risk CIP medical record research studies (AR 40-66, 2-8) may be exempt from ICD requirements (AR 40-38, Appendix B). HIPAA authorization is required if these studies use PHI (DoD 6025.LL-R, C7.9).

2. HIPAA authorization for some minimal risk CIP research studies that use PHI may be waived by an IRB or privacy board. HIPAA authorization waiver criteria are described in 45 CFR 164(i)(2)(ii) and DOD 6025.LL-R C7.9.2.2.

a. Privacy boards [see 45 CFR 164.512(i)(1)(i)(B)] may approve waiver of HIPAA authorization when appropriate. However, it may be easier for established IRBs to waive HIPAA authorization.

b. IRBs can use the expedited review process to waive HIPAA authorization.

3. We recommend that the HIPAA Authorization Form be separate from the study ICD. Realizing that this requires subjects to sign twice, it provides a clear delineation of the HIPAA authorization, and it allows modification of the authorization, if necessary, without having to amend the study ICD. If HIPAA authorization language is embedded in the study ICD, then study ICDs approved prior to HIPAA implementation and still enrolling subjects will need to be amended and approved by the IRB.

4. Subjects enrolled in approved research studies prior to 14 April 2003 will not require HIPAA authorization in conjunction with the previously signed ICD unless the ICD has been amended and the IRB requires re-consent of previously enrolled patients.

5. Documentation of HIPAA authorization is accomplished by providing a copy of the authorization form when submitting the protocol for review and approval. HIPAA authorization waiver must be documented in the IRB (or privacy board) minutes. Waivers must be in accordance with 45 CFR1 64.512(i)(2)(ii) and DOD 6025.LL-R C7.9.2.2. Attaching an Application for Waiver of Authorization to the minutes is an easy way to satisfy the documentation requirements.

6. CIRO will monitor for research study compliance with HIPAA after 14 April 2003. Please do not hesitate to contact CIRO staff if questions arise.

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