OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
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HEALTH AFFAIRS

AUG 13 2009

MEMORANDUM FOR DEPUTY DIRECTOR, TRICARE MANAGEMENT ACTIVITY

SUBJECT: Establishment of a TRICARE Management Activity Privacy Board and Revision of Section C7.9.1 of Department of Defense Health Information Privacy Regulation (DoD 6025.18-R)

This memorandum approves your request for an exception to policy permitting the establishment and use of a TRICARE Management Activity (TMA) Privacy Board for the limited purpose of reviewing research requests for an alteration to or waiver of individual authorizations in which the research involves Military Health System (MHS) Protected Health Information (PHI) owned and/or managed by TMA and the Department of Defense (DoD) Component is not otherwise able to meet the Health Insurance Portability and Accountability Act (HIPAA) and DoD 6025.18-R requirements through their own Institutional Review Board (IRB). Additionally, I authorize revisions of DoD 6025.18-R, Section C7.9.1, to be consistent with the broader provisions for research related uses and disclosures under HIPAA, at Title 45, Code of Federal Regulation (CFR), Section 164.512(i).

The rationale for this decision is as follows:

HIPAA permits the use and disclosure of PHI for research in which documentation is obtained approving an alteration to or waiver, in whole or in part, of the individual authorization by either an IRB or a Privacy Board. (45 CFR Section 164.512(i)). DoD 6025.18-R (implementing HIPAA), at Section C7.9.1, is more stringent than HIPAA and states:

a. In the case of research conducted or supported by a DoD Component, an alteration to or waiver, in whole or in part, of the individual authorization for use and disclosure of PHI can only be approved by an IRB established in accordance with 32 CFR 219.107. (DoD 6025.18-R, Section C7.9.1.1.)

b. Where research is conducted or supported not by a DoD Component but by another Federal Agency, an alteration or waiver of this type must be approved by an IRB established in accordance with the Agency's regulation comparable to 32 CFR 219.107. (DoD 6025.18-R, Section C7.9.1.1.1.)

c. Research that is not conducted or supported by a Federal Agency must be approved by a Privacy Board. (DoD 6025.18-R, Section C7.9.1.1.2.) TMA does not have an IRB, aside from the IRB within the Uniformed Services

University of the Health Services and most DoD Components do not have IRBs that are set up to meet the HIPAA and DoD 6025.18-R privacy requirements. Currently, there is a compliance gap for research studies using MHS PHI owned and/or managed by TMA, in that neither TMA nor DoD Components are easily able to satisfy the HIPAA and DoD 6025.18-R requirements.

Establishment of a TMA Privacy Board addresses the gap in compliance in that it can review research requests for an alteration to or waiver of the individual authorization where the research involves MHS PHI owned and/or managed by TMA and the DoD Component is not otherwise able to meet the HIPAA and DoD 6025.18-R requirements through their own IRB. This action resolves the current privacy dilemma in that research supported or conducted by DoD Components needing MHS PHI owned and/or managed by TMA will otherwise come to a halt.

The establishment and use of a TMA Privacy Board to fulfill this requirement is consistent with the HIPAA regulations, but as noted above will ultimately require a change in DoD 6025.18-R at Section C7.9.1 to include Privacy Board approval, as well as IRB approval (as permitted under HIPAA). Revision of DoD's regulation at Section C7.9.1 to mirror HIPAA will not only permit a TMA Privacy Board within TMA to meet the regulatory requirements in this regard but would further allow the DoD Components to ultimately set up their own Privacy Boards to meet HIPAA and DoD requirements and will promote greater compliance with the privacy regulations.

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Performing the Duties of the
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