TDH
TEXAS DEPARTMENT OF HEALTH

Texas Department of Health

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Dear HIPAA covered entity:

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Standards (Privacy Standards) codified at 45 CFR, Parts 160 and 164, were implemented on April 14, 2003. The Texas Department of Health (TDH), Office of General Counsel has been ask by various programs that conduct or approve research, whether the implementation of the Privacy Standards will affect ongoing research projects with IRB approval obtained prior to the implementation date. We have also been asked how future research will be affected by the Privacy Standards.

The short answer is "no". If a research project has gone through an IRB approval process established under various federal statutes or following the Common Rule, or a Privacy Board (PB) in compliance with the HIPAA Privacy Standards at 45 CFR §164.512(i), HIPAA will provide no barrier to using protected health information (PHI), without the authorization of the person to whom the PHI relates.

Under the Privacy Standard for Research in 45 CFR §164.512(i), a covered entity can continue to release PHI for research purposes, regardless of the source of funding if the research meets the following requirements:

1. **Authorization**. A waiver of the authorization (otherwise) required under the HIPAA Privacy Standards at 45 CFR §164.508, has been authorized by an IRB or PB;
2. **Preparation.** The researcher represents that PHI is necessary for preparation of research, no PHI will be removed in the course of the review, and the PHI is necessary for research purposes. This applies to PHI of both living and deceased individuals.
3. **Documentation.** The required waiver is documented, including the identification of the IRB or PB and date of approval; that the waiver meets the criteria of 1) no or minimal risk to individuals 2) research cannot be conducted without the waiver 3) research requires access and use of PHI; a description of the PHI needed; that the waiver has been reviewed and approved under normal or expedited review procedures; and the documentation is signed by the chair or other designated member of the IRB or PB.

The HIPAA Privacy Standards recognize the importance of access to protected health information in research and provide for the above broad exception to the requirement to obtain authorizations from individuals for use and disclosure of PHI, as long as the research meets existing federal IRB or PB processes.

Additionally, the state law, Health and Safety Code, §181.102, that had the potential of creating differences in

Texas research criteria, and federal IRB standards and criteria and HIPAA Privacy Standards was repealed by SB 330, 78th Legislative Session, which was signed into law on April 11, 2003, prior to the September 1, 2003, effective date of §181.102.

I hope this letter helps explain the exception in 45 CFR §164.512(i) of the HIPAA Privacy Standards that allows current and future research that fall within the exception to continue.

Sincerely,

Joan Carol Bates
Assistant General Counsel
Office of General Counsel