Division of AIDS Review of Informed Consent Forms: Impact of the HIPAA Privacy Rule

Background:

The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by the Department of Health and Human Services (DHHS), Office of Civil Rights (OCR). The Privacy Rule complements existing regulations for the protection of human subjects as found in the Common Rule (45CFR46) and FDA Regulations (21CFR50); it does not modify nor replace these current regulations. Covered entities must comply with the Privacy Rule by April 14, 2003.

Issue:

The Division of AIDS (DAIDS), through the Regulatory Affairs Branch (RAB), with support by the Protocol Registration group of the Regulatory Compliance Center (RCC), is responsible for the review and approval of the protocol Sample Informed Consent Forms and IRB-approved site-specific informed consent forms for all DAIDS-sponsored network protocols. These consents must meet OHRP/FDA regulations as well as DAIDS requirements. In addition, sites and/or institutions that are covered entities will be required to meet HIPAA Privacy Rule requirements. Covered entities may elect to incorporate Privacy Rule language into their site-specific informed consent forms, and such consent forms are subject to regulatory review by DAIDS for compliance with 45CFR46 and 21CFR50, but not for compliance with the Privacy Rule.

Grantees and their IRBS need clarification from DAIDS about how the new Privacy Rule will affect Protocol Registration for DAIDS-sponsored trials.

DAIDS Requirements for Consent Review:

Consent Forms Incorporating HIPAA Authorization

- Site-specific informed consent forms containing language pertaining to HIPAA authorization will be assessed by RAB/RCC for compliance with Common Rule and FDA regulations and DAIDS requirements, but NOT for Privacy Rule compliance.
- To facilitate the review of consent forms, it is requested (but not required) that Privacy Rule language in the site consent be highlighted (e.g., bold type, italics).

- If it is determined that a site consent form does not meet Common Rule and FDA regulations and/or DAIDS requirements, it will be disapproved according to routine RAB/RCC procedures currently in use.
- A disclaimer will accompany all electronic informed consent approvals and disapprovals sent by DAIDS Protocol Registration to sites. It will indicate that the review decision is based on meeting the Common Rule, FDA regulations and DAIDS requirements and that DAIDS Protocol Registration review of informed consents for implementation does not certify or affirm HIPAA compliance.

Separate HIPAA Authorization Forms from Sites

- Separate HIPAA authorization forms are outside the purview of DAIDS Protocol Registration.
- Separate HIPAA authorization forms that are included with Protocol Registration materials will be returned to the institution/site without DAIDS review.
- It is recommended that institutions/sites follow the procedures of their IRBs and/or Privacy Boards for obtaining HIPAA authorization.

RAB/RCC Pre-Review of Site-Specific Consent Forms

- If requested, RAB/RCC will pre-review site-specific consent forms prior to IRB submission to ensure compliance with the Common Rule and FDA regulations and DAIDS requirements. RAB/RCC will NOT pre-review consent forms for Privacy Rule compliance.
- To facilitate the review of consent forms, it is requested that Privacy Rule language be highlighted (e.g., bold type, italics).

The above policy is based on the current NIH guidance and may be updated when more information becomes available.

Information related to the Privacy Rule can be found at the following website: www.hhs.gov/ocr/hipaa