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Making Your IRBs and Clinical Investigators HIPAA-Ready

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Privacy: Present and Future

Today:

- The Common Rule
- FDA Human Subject Protection Regulations
- State medical confidentiality laws

Tomorrow (April 2003):

- The Common Rule
- FDA Human Subject Protection Regulations
- State medical confidentiality laws
- HIPAA Administrative Simplification requirements

New things to think about

New Proposed Privacy Rule Comment:

. . .the intent of the Privacy Rule, among other things, is to supplement these protections by requiring covered entities to implement specific measures to safeguard the privacy of individually identifiable health information."

Common Rule

IRB must determine that, *when appropriate*, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. § 46.111(a)(7)

Informed Consent must include a statement describing the extent, *if any*, to which confidentiality of records identifying the subject will be maintained.

FDA Human Subject Regulations

The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with applicable regulatory requirements. (Clinical Investigator Guidelines)

IRB must determine that, *where appropriate*, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. 21 CFR § 56.111(a)(7)

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HIPAA building upon existing federal regulations

Express authorization for disclosure and use of PHI for research (separate or as part of the IRB approved informed consent).

Special requirements to qualify and obtain a waiver of authorization and consent in addition to Common Rule waiver requirements.

Different standards of what data is sufficiently de-identified.

Identification and notice to research subjects of the persons receiving, using and the information used and disclosed.

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Developing Compliance Tools for IRBs and Clinical Investigators

Increase awareness of risks and the need for CIs and Sponsors to cooperate.

Look at Study Design to address privacy concerns:

- Minimum necessary
- Securing records from public view/access
- Procedures for collection, storage & retrieval of data

De-identification of data (comment to DHHS).

Accreditation Standards - AAHRPP

Confidentiality Module in Training

Issues to Address

Informed Consents v. Separate Authorizations.

Covering the elements required in Privacy Rule at §§ 164.508(c) and 164.508(f).

How to handle waivers . . . IRB v. Privacy Board.

Documentation of waiver requirements to establish minimal risk by CI and review by IRB/Privacy Board.

Transition to new rule and reliance on previous waivers, consents and authorizations Grandfather provisions.

List of things to do

Review and modify existing policy and procedure on privacy/confidentiality to include additional HIPAA requirements.

Develop Compliance Checklist that deals with Privacy/Confidentiality Issues. (See handout).

Template for Confidentiality/Privacy section in Informed Consents.

Workshops and other training for IRB members and CIs.

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Resources

Workgroup on Electronic Data Interchange (WEDI); http://snip.wedi.org/

Department of Health and Human Services Administrative Simplification; http://aspe.hhs.gov/admnsimp/Index.htm

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

AMC Guidance on HIPAA regulations

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Thank You!