Managing Privacy Risk in Your Research and Development Enterprise

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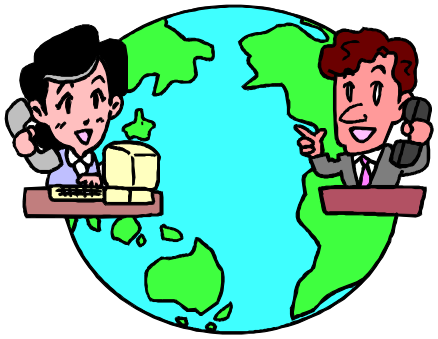
Why Privacy Matters

- Human subject data is extremely sensitive



- Access to data is critical to pharma business
  - ➢ Clinical research
  - ➢ Pharmacovigilence

- Mistakes and lack of safeguards can lead to:
  - ➢ Adverse media attention
  - ➢ Litigation
  - ➢ Loss of trust
  - ➢ Increased regulation

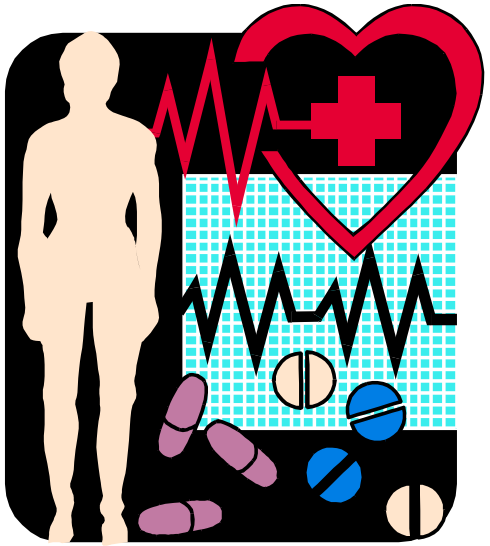
- Researchers, CROs, and IRBs all play a role in protecting privacy of research data

Challenges

- Increase regulatory hurdles to prove effectiveness and safety of products require Pharma to conduct longer and costlier clinical trials
- Many programs are conducted at multiple sites and countries
- Differing interpretations of privacy requirements exist among stakeholders
- Public and press are beginning to question adequacy of research subject protections

The Good News...

- Pharma companies have a long history of managing patient data in clinical trials
- Individuals dedicated to:
  - SOP/guideline development
  - Human subject protections
  - Consent process
  - Communication
  - Training



HIPAA Overview for Sponsors

- Pharma companies are not HIPAA "covered entities" (CEs)
  - ➢No direct obligation on pharma sponsors of research to obtain HIPAA authorizations, etc.

However,

- Pharma's access to patient data could be at risk if covered entities do not obtain proper authorizations

HIPAA's General Rule Covering Research

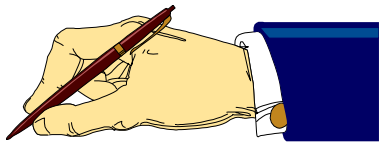
Covered entities may only use or disclose PHI to pharma for research purposes in limited circumstances:

1. Individual Authorization
2. Waiver of Authorization
3. Reviews Preparatory to Research
4. De-identified Data and Limited Data Sets

HIPAA Issues in Research

- Clinical Study Start-Up
  - ➢Identification of Subjects
  - ➢Verification of Eligibility
  - ➢Subject Recruitment

- Study Conduct
  - ➢Authorizations



- Post-Study Activities
  - ➢Data Analysis
  - ➢Long-term Follow up

Subject Identification

Question: How can CE use PHI to identify eligible subjects?

Options under HIPAA:

1. Reviews Preparatory to Research
   - Permits CEs to use/disclose PHI to assist in development of research protocol and aid in recruitment of subjects
   - PHI cannot be removed from CE's site, but records may be flagged
   - PHI disclosed must be necessary for research purpose
   - Sponsor may not contact subject unless authorized

Subject Identification

2. IRB or Privacy Board Partial Waiver of Authorization

Criteria:

- Use/disclosure of PHI results in no more than a minimal risk to privacy
- Research could not practicably be conducted without waiver
- Research could not practicably be conducted without access to the information

Issues with Subject Identification

- Uncertainty about extent to which information can be collected and shared without waiver or authorization
- Sponsors generally not part of process, so sponsor is not always informed when waivers are requested
- Waivers for subject identification may be requested when review of records could otherwise take place under exception for reviews prep
- Partial waivers may impose limitations on trial
- Individual requests from sites in multi-site trials
  - ➢ Recent HHS guidance confirms use of multi-site waivers, but operational aspects are unclear

➡ Potential for increased costs and delays in recruitment and enrollment

Subject Recruitment

Question: How can researchers *contact* eligible subjects?

Options under HIPAA:

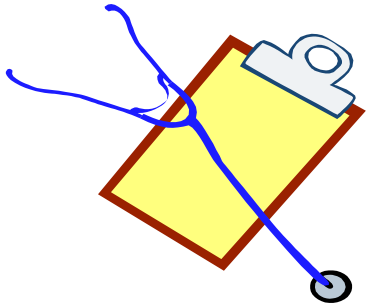
1. Disclosure to the individual
   - CEs may speak directly with individuals about option of enrolling in clinical trial. Individuals could then contact pharma company or third party contractor about interest
   - Non-CE cannot initiate contact with individuals absent waiver or authorization
2. Partial waiver
3. Authorization for recruitment
   - Blanket authorizations for future recruitment not permitted

Issues with Subject Recruitment

- Waivers sometimes requested when face-to-face exception applies.
- During recruitment process some investigators ask whether they can transmit certain subject information to sponsor for validation of subject eligibility.
- If recruiter is not a covered entity, then HIPAA does not apply.

Conduct of Study

Question: Once study commences, how can data be collected and transferred?



Options under HIPAA

- HIPAA Authorization (primary vehicle)
- De-Identification
- Limited Data Sets

Key Issues with Authorizations

- Consider whether to include authorization in informed consent document
  - Recent HHS Guidance on IRB review of authorizations
  - Reaction from IRBs
- Battle of forms
  - Consider use of IRB versus sponsor-generated authorization
  - Consider legal implications of using deficient authorization offered by CE or IRB
  - Consider time/resources impact on clinical study
- Secondary research issues

Secondary Research

Issue: Authorizations must indicate purposes of uses and disclosures of PHI with specificity. PHI disclosed to sponsor is no longer protected by Rule. HHS has indicated that authorizations for future unspecified research *by covered entities* are overly broad, and authorizations must be "study specific".

- Does "study specific" mean protocol specific?
- If potential future uses can be described with specificity, is this permitted?
- What should sponsors do if IRB/CE refuses to reference future uses in authorization?
- Is it a misrepresentation to fail to indicate how PHI may be used in future by sponsors?
- Do de-identification or limited data sets provide practical options?

Secondary Research in Genomics

Issue: Researchers may collect samples for future genetic testing. How can these samples be used and disclosed?

- DNA and tissue samples that cannot be linked to an individual are not PHI
- Data is PHI if individual identification of data is possible through comparison of DNA sequence characteristics to existing databases
- What is the status of sample banks under HIPAA?
  - ➢ Can uses be specified?
  - ➢ Can samples be de-identified?
  - ➢ If samples in historic databases will be used, must new consent be obtained if new purpose is intended for sample?

Long-Term Follow Up

Issue: FDA encourages long-term follow up with subjects in clinical trials.

- What are the implications under HIPAA?
- When may subjects be contacted and for what purpose?
- Must new HIPAA authorizations be executed?

Managing HIPAA Issues

Managing Privacy

- Understand privacy concerns and perceptions
- Make management aware of privacy risks
  - Obtain resources for addressing privacy
- Confirm that written procedures, consents, and authorizations accurately reflect actual practices
- Engage in constructive outreach to IRBs, FDA, HHS, others
- Communicate with other pharma companies to share experiences and understand trends

IPPC

International Pharmaceutical Privacy Consortium

- 15 member company association dedicated to developing compliance tools and best practices for privacy
- IPPC Working Group on Clinical Research
  - ➢ Developed template authorization
  - ➢ Dialogued with OCR, FDA, HHS, IRBs regarding authorization issues
  - ➢ Engaging in outreach to broader research community
  - ➢ Analyzed issues involved in secondary research, subject identification, and recruitment

Best Practices

- Authorizations
  - Authorizations should be clear, concise, and comprehensive
- Secondary Research
  - Inform subjects that personal data will be maintained in databases and possibly used for future research
- Subject Recruitment
  - Provide clear guidance to investigators and third party contractors when waivers are required and when they are not required for recruitment