Advanced HIPAA Issues for Biotech and Life Sciences Companies:

On the Frontier of Science and On the Edge of HIPAA

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HIPAA Provisions under which Biotech / Life Sciences Issues Arise

- HIPAA provider coverage?
- Business Associate applicability?
- Authorizations – unspecified research
- Research data bases
- Accounting for research disclosures
- Clinical studies in E.U. – HIPAA interface

Medical Device / Testing Companies – Covered Entities?

- May be “health care provider” under broad HIPAA definition
- Most don’t engage in electronic standard transactions
- Some may unwittingly send claims, insurance or related e-mails
- If so, possible HIPAA coverage
- Not all ask right questions of right people
  - To properly determine status

If covered, then what?

- Privacy notices, etc.
- To whom?

Are Clinical Researchers / Sponsors or CRO's Business Associates?

- Generally "research" not a BA function performed for covered entities
- "We're not a BA" letter
- BA's often negotiated
  - Business clout
- If researcher / sponsor also provides
  - Quality assurance, or
  - Data processing services for covered entity
    - De-identifying records, or
    - Creating limited data sets
  - Then researcher / sponsor *is* BA
- Researcher / sponsor – document in CTA that no BA-triggering services provided

Sponsors Generally Not Covered Entity or BA

No HIPAA concerns, then, right? ***Not so fast . . .***

- Sites will and should impose handling restrictions in CTA's
- Some sites impose informed consent confidentiality limitations
  - Blending with HIPAA standards, on researchers / sponsors and "downstream"
  - Restricts marketing use

Sponsors Generally Not Covered Entity or BA

- Confidentiality agreement OK, but modify agreements
  - To specifically allow
    - For monitoring services, and
    - Other purposes in HIPAA-compliant patient authorization
- Other agreement “pass-throughs”
  - Reps and warrantees, indemnity language
- Researchers / sponsors – rigorous privacy policies / practices that approximate those of HIPAA
  - HIPAA treated as de facto standard of care
    - State law invasion of privacy claims

Authorizations – Future Unspecified Research

- HIPAA authorizations for research
  - Can broadly cover patient's entire medical record
  - Can broadly cover classes or persons to whom and by whom PHI can be used / disclosed
  - Under "purpose" element,
    - "Each purpose" must be specified
    - Valid authorization for **unspecified** studies
      - Virtually impossible under HIPAA
      - Registry or database for unspecified future research – OK

Research Databases under HIPAA

- Database – separate purpose from primary protocol
- Must be specifically authorized
  - In protocol authorization or
  - In separate subsequent authorization
- If database maintained by covered entity
  - Future disclosures must be pursuant to new authorization
- If database disclosed to sponsor
  - Generally outside HIPAA

IRB Waivers and Future Researcher Follow Up with Participants

If IRB Waiver

- Researcher free to use PHI for current research
- New, specific waiver necessary
  - Before researcher can contact study participants about *new* study

Accounting for Research Disclosures

- **NEED NOT** be accounted for where
  - Disclosed under authorization
  - Disclosed in limited data set form
    - Needs data use agreement
- **MUST** be accounted for upon individual request where disclosed pursuant to IRB waiver
- Less detailed accounting:
  - Where covered entity discloses records of ▫ 50 individuals under IRB waiver during requested accounting period

Coming HIPAA Attractions: *Clinical Studies Abroad and Outsourcing*

E.U. Model different – no HIPAA statute but broader data laws

- E.U. Data Protection laws
  - Each E.U. country
- Consent necessary for medical data use (sensitive data)
  - Specific use, purpose, etc.
  - English or in local language?
- Data transfer out of E.U. country to U.S.
  - Consent to transfer – different from consent to use / collect
  - Data protection model clauses / agreements
  - U.S. Safe Harbor

Who Follows Up on E.U. Branch Office or E.U. Consents?

- Some companies not aware of or abide by these laws
- Risk to studies?
- Sometimes requires explanation of importance
- E.U. clinical directive

Is foreign medical PHI subject to HIPAA when transferred to U.S. HIPAA covered entity?

- Telemedicine
- Medical records of E.U. resident sent to U.S.

Outsourcing of HIPAA Data Processing Overseas

- Canada, India, Pakistan, Philippines
- Medical transcription services
- Pakistan case – multiple contractors to HIPAA covered entity
- Rep. Markey letter to HHS
- Possible outsourcing amendments to HIPAA