



Company-Sponsored Epidemiology under HIPAA

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Epidemiology: A Research Function of DuPont

- HIPAA Privacy Rule permits uses/disclosures of protected health information (PHI) for purposes of research and research activities, provided the Covered Entity complies with specific standards for such use.
- The DuPont Epidemiology Program is primarily a research function and therefore falls within this category for permitted use of PHI.



DuPont Epidemiology is an “old” program...

- Formally initiated in 1956 with Cancer Incidence and All-cause Mortality Registries
- Things in place:
 - Good Epidemiological Practices
 - ACE Ethics Guidelines
 - Standard operating procedures
 - Quality Assurance (Haskell is a GLP lab)
 - DuPont Global Information Privacy Policy
 - External Epidemiology Review Board



Why do we have to comply with HIPAA?

- DuPont in its entirety is a Covered Entity (CE)
- A **covered entity** is a **health plan**, health care clearinghouse, or health care provider who transmits health information in electronic form.
- A **health plan** is any individual or group plan that provides or pays the cost of medical care : DuPont is self-insured
- DuPont Epidemiology Program is part of the CE
 - Ascertainment of cancer cases for Cancer Registry is primarily through **health insurance benefits data, transmitted electronically** to Registries Supervisor
 - Epidemiology needs to show compliance with the specific applicable standards that govern the Program's responsibilities and tasks.

HIPAA Standards and Applicability to Epidemiology

Section	Description	Applies
	Uses/Disclosures of Protected Health Information	
§ 164.502	General Rules	Yes
§ 164.504	Organizational Requirements	Yes
§ 164.506	To Carry Out Treatment, Payment, and Health Care Operations	No
§ 164.508	For Which an Authorization is Required	Yes
§ 164.510	Requiring an Opportunity for the Individual to Agree or Object	Yes
§ 164.512	For Which Consent, an Authorization, or Opportunity to Agree or Object is Not Required	Yes
§ 164.514	Other Requirements Relating to Uses/Disclosures	Yes

HIPAA Standards and Applicability to Epidemiology

Section	Description	Applies
	Privacy and Access to PHI	
§ 164.520	Notice of Privacy Practices for PHI	Yes
§ 164.522	Rights to Request Privacy Protection for PHI	Yes
§ 164.524	Access of Individuals to PHI	No
§ 164.526	Amendment of PHI	No
§ 164.528	Accounting Disclosures of PHI	No
§ 164.530	Administration Requirements	Yes
§ 164.532	Transition Requirements & Compliance Dates	Yes



Tasks Required for Compliance

- Amend Charter of the Epidemiology Review Board to qualify the ERB as a Privacy Board
- Develop Privacy Board Waiver of Authorization for Research Purposes
- Document Training Records for Epidemiology Staff



Tasks Required for Compliance

- Quality Directive (policy) committing Haskell to comply with HIPAA
- New Standard Operating Procedures
 - “Minimum necessary” for use, disclosure or requests for PHI
 - Exclusions/Exceptions to HIPAA Privacy Rule
 - Safeguards for PHI



Tasks Required for Compliance

- Review existing SOPs for:
 - Assuring Deceased have equal rights to Living
 - Assuring consistency with HIPAA privacy rule
 - Assuring that Business Associates' Contracts/Agreements are compliant
 - Assuring consistency with DuPont Global Information Privacy Policy



HIPAA, GIPP, and the EU Privacy Directive

- DuPont **G**lobal **I**nformation **P**rivacy **P**olicy modeled on the European Directive
- Applies globally to all data—HR or commercial use
- Applies to individually identifiable data, not aggregated data
- DuPont PITA—Personal Information Transfer Agreement



International Studies

- Two international studies ongoing, requiring data transfer to and from the U.S. and
 - United Kingdom
 - Republic of Ireland
 - Netherlands
 - France
 - Italy
 - Germany



International Studies

- EU Directive prohibits transfer of data to another country without ensuring that an “adequate level of protection” exists.
- July 2000, EU Commission concluded that U.S. Safe Harbor Privacy Principles were an adequate level of protection.
- U.S. HHS issued a statement to the effect that the Safe Harbor Privacy Principles and the HIPAA Privacy Regulation are based on common principles of fair information practices and are “essentially consistent.”



International Studies

- HHS Statement

“...an organization complying with our [HIPAA] privacy regulation can fairly and correctly self-certify that it complies with the [Safe Harbor Privacy] Principles.”

- Therefore, DuPont can engage in appropriately designed and reviewed studies that include European Union member countries.