R & D Privacy Issues for Pharmaceutical Manufacturers

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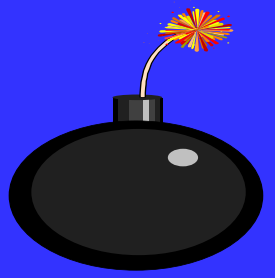
Privacy Issues For Sponsors of Clinical Research

- HIPAA
  - Screening subjects & protocol development
  - Recruiting subjects
  - Revisions of protocols and consent forms
  - Site monitoring
  - Private databases and repositories
  - Increased liability
- Multi-site trials
  - Coordination of HIPAA and state privacy laws
    - Medical privacy
    - Genetic privacy
  - Compliance with international privacy laws

HIPAA's Components

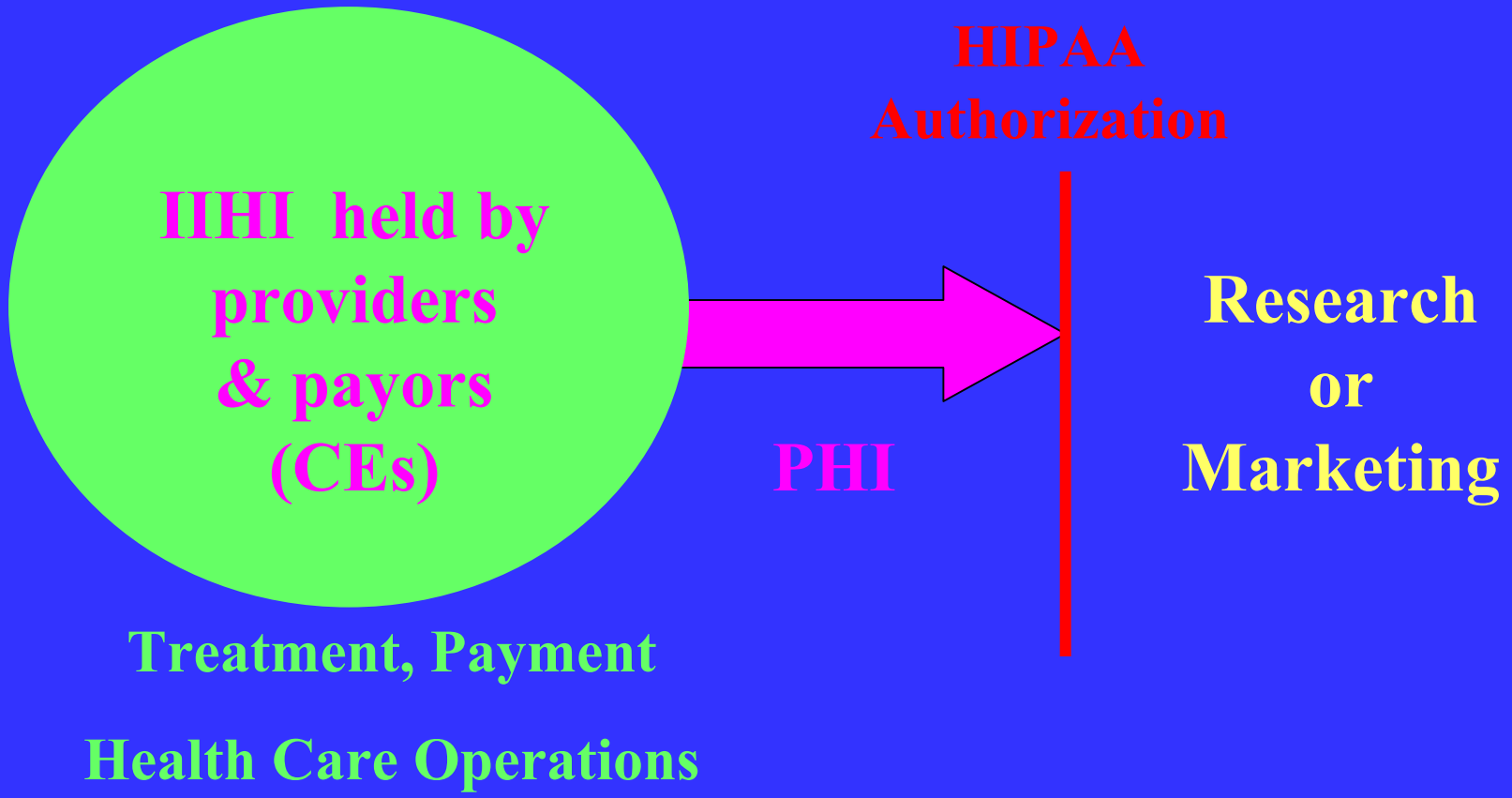
- **Standard Transactions and Code Sets**
  - **Final rule: August 2000**
  - **Compliance deadline: October 16, 2002**
- **Security Regulations**
  - **Final rule: February 13, 2003**
  - **Compliance deadline: February 2005**
- **Privacy Regulations**
  - **Final rule: August 14, 2002**
  - **Compliance deadline: April 14, 2003**



HIPAA's Privacy Rule: General Principles

- Allows for the smooth flow of individually identifiable health information (IIHI) for treatment, payment and business operations
- Prohibits the flow of IIHI for other purposes unless explicitly and voluntarily authorized by the subject
- Provides rights to individuals to have access to their IIHI and know who is using their IIHI and how it is being used
- Provides legal enforcement

HIPAA's Privacy Rule: General Principles



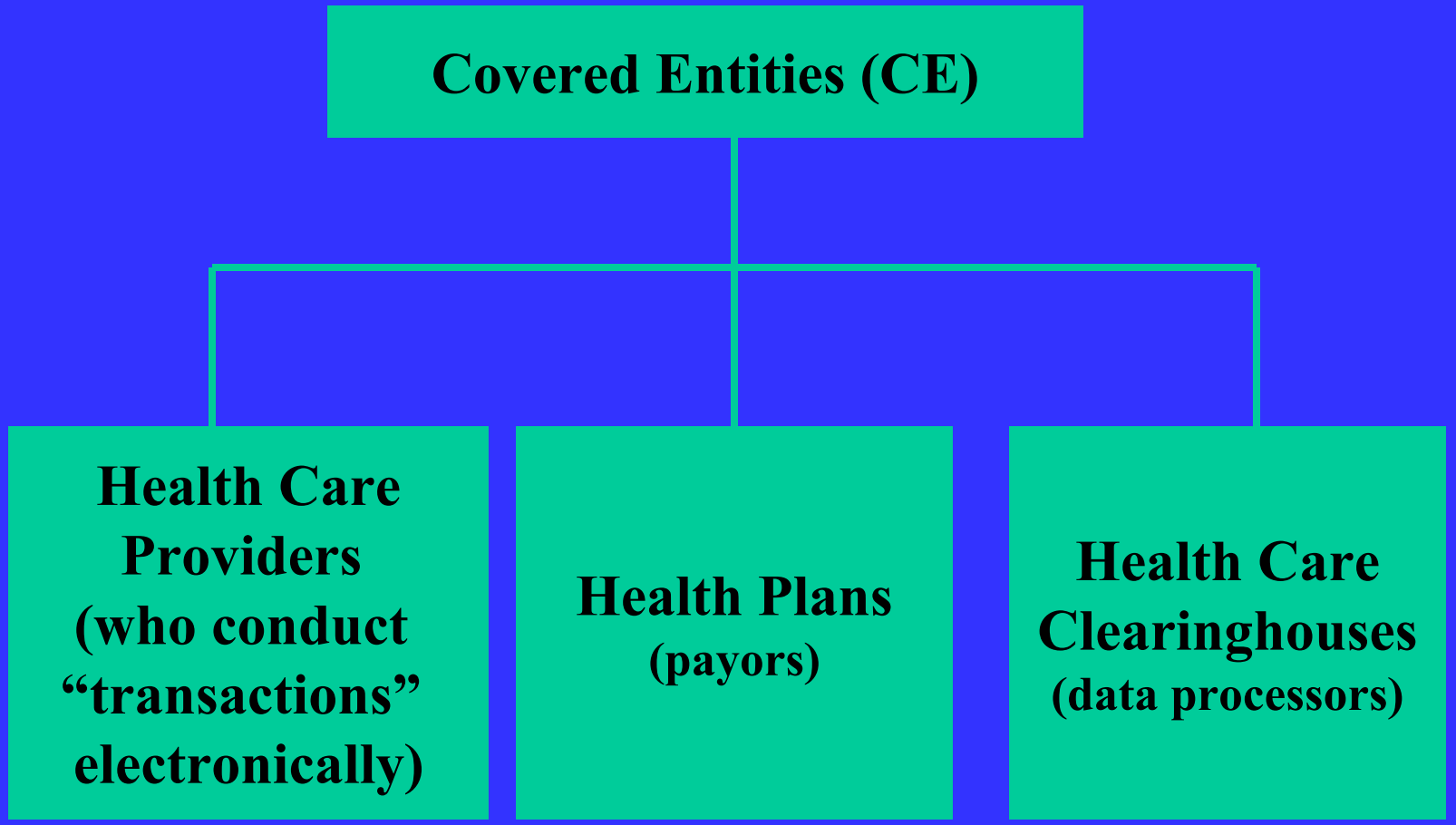
HIPAA's Privacy Rule For Research

- A covered entity (CE) may not *use* or *disclose*
- Individually identifiable health information (IIHI)
- Without *written* authorization – UNLESS
  - One of a limited number of exception applies

HIPAA's Privacy Rule Applies to *Use* or *Disclosure* of PHI

- ***"Use"* includes:**
  - **Internal use within the CE**
  - **Review, analysis, "looking at" (*e.g.*, chart reviews)**
- ***"Disclosure"* includes:**
  - **External use outside the CE**
  - **Release, transfer, providing access to PHI or code**
  - **Includes sponsors, study monitors, CROs**

Who Is Covered?



Covered Entities: Health Care Providers

- Furnish or provide, bill or receive payment
- For "health care"
  - Care, services or *supplies*
  - Includes
    - Direct providers (physicians, nurses, social workers, pharmacists, etc.)
    - Indirect providers (*pharmaceutical companies*, DME suppliers, etc.)
  - Even if provided only in clinical trials
- And electronically transmits health information for a HIPAA "transaction" (billing/admin. for health care)

Who is a Covered Entity?

- **Physician/researcher? Yes**
  - **HIPAA will affect use/disclosure of PHI for any research activity (subject screening, recruitment, research)**
- **CRO? Usually no.**
- **Sponsor? Usually no, but:**
  - **In-house health clinics IF bill electronically**
  - **May be a health plan (self-insured plans, Flexible Spending Accounts, ERISA Health Benefit Plans for employees)**

What is Covered?

- **Protected health information (PHI) is:**
  - **Individually identifiable health information**
  - **Created or received by a covered entity**
  - **Transmitted or maintained in *any* form or medium (not just electronic)**

Will HIPAA Affect Sponsors? YES!

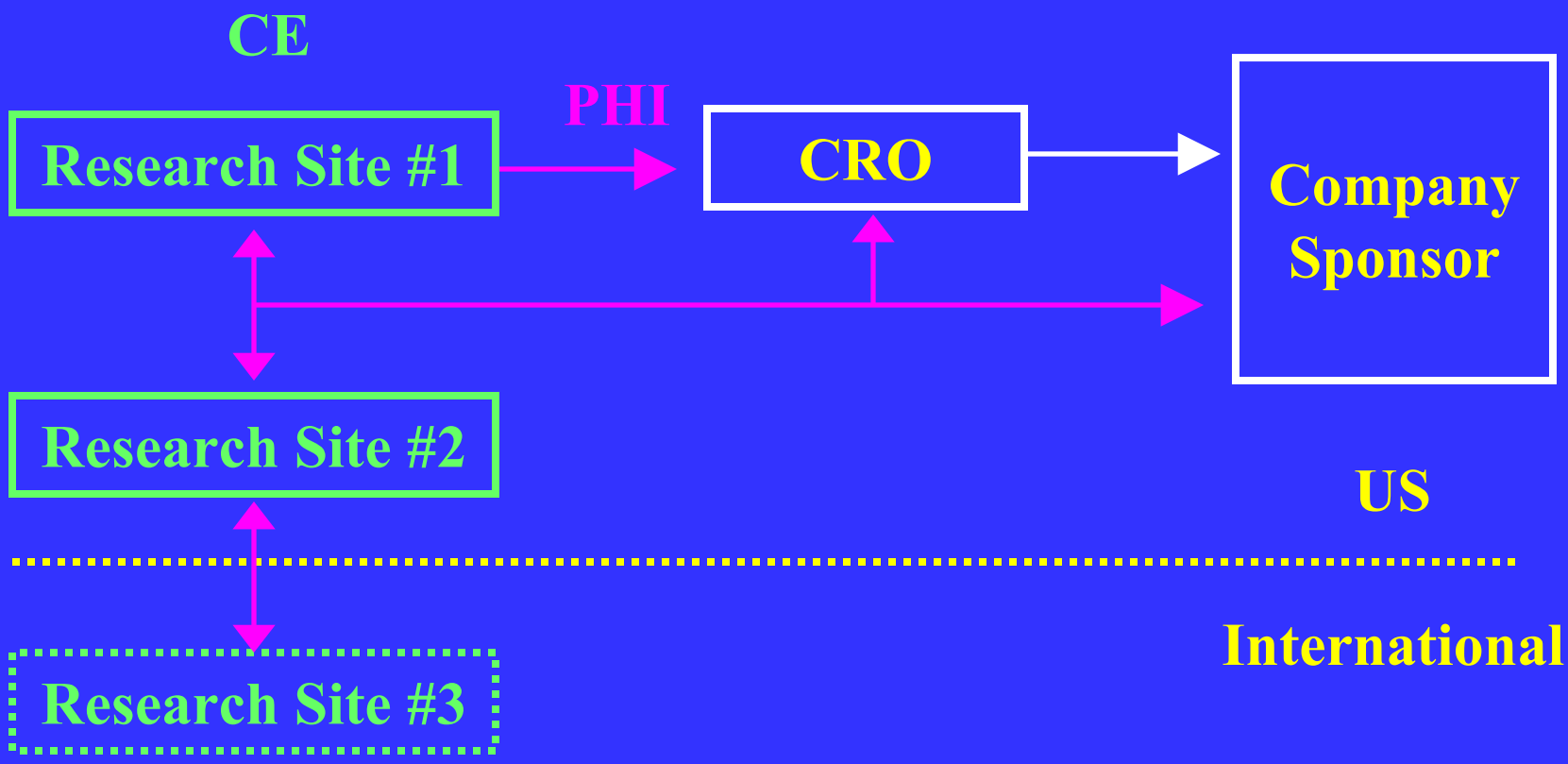
Sponsors Business Objective:

Obtain the best possible *data*
in the shortest amount of *time*

Impact of HIPAA On Sponsors

- Sponsors must ensure a viable business model for clinical research
  - Protocols must include HIPAA compliant procedures for the flow of PHI
  - Research contracts must reflect HIPAA obligations
  - Coordinate HIPAA, state and international privacy laws
- Exposure to liability for privacy violations

Research Models Must Ensure Flow of Data From Data Source to Endpoint



HIPAA's Hammer

HIPAA will increase the liability risk for failure to protect privacy in medical research

HIPAA's Enforcement Provisions

Who is subject to HIPAA's penalties?

- **Any "person" who**
- ***Obtains* or discloses PHI in violation of HIPAA**

- **Civil penalty**
  - **$100 each violation, up to $25,000/person/year**
- **Criminal Penalties**
  - **Knowingly: ≤ $50,000, 1 yr. jail**
  - **False pretenses:≤ 100,000, 5 yrs. jail**
  - **With intent to sell, transfer, or use for commercial advantage or personal gain: ≤ $250,000, 10 yrs. jail**

Does HIPAA Apply?

- A covered entity may not *use* or *disclose*
- Protected health information (PHI)
- Without written *authorization* – UNLESS
  - An exception applies

Research + CE + PHI = HIPAA Authorization

Does HIPAA Apply?

Research + CE + PHI = HIPAA Authorization

1. ***Is it "research"?***
2. **Is a "covered entity" involved?**
3. **Is it "PHI"?**

What "Research" is Affected by HIPAA?

- HIPAA = Common Rule
- Any *systematic* investigation,
- Designed to develop or contribute to *generalizable* knowledge (not just for knowledge or treatment of that subject) and
- Involves *human* subjects
  - HIPAA: applies to living and *deceased* persons
  - Common Rule and FDA regulations: apply only to "living" persons

Research Activities Affected by HIPAA

- Feasibility studies
- Subject screening
- Subject recruitment
- Subject enrollment and creating new PHI
- Use of existing PHI in databases, repositories, medical records, health services records, etc.

Research + CE + PHI = HIPAA Authorization

Does HIPAA Apply?

Research + CE + PHI = HIPAA Authorization

1. **Is it "research"?**
2. ***Is a "covered entity" involved?***
   - ***Already covered***
3. **Is it "PHI"?**

Does HIPAA Apply?

Research + CE + PHI = HIPAA Authorization

1. **Is it "research"?**
2. **Is a "covered entity" involved?**
3. ***Is it "PHI"?***

What is PHI?

- **Individually identifiable health information (IIHI)**
- **From a living or deceased person**
- **Created or received**
- **By a covered entity**
- **Transmitted or maintained in *any* form or medium (not just electronic)**
- **Includes *demographic* information (affects use of PHI for recruitment)**
- **Includes some *coded* data**

Use or Disclosure of *Coded* PHI

- **A covered entity may assign a code for re-identification ("re-identification code"), provided**
  - **Derivation: The code *is not derived from or related to information about the individual* and cannot be used to identify the individual; AND**
  - **Security: The covered entity *does not use or disclose the code* or other means for re-identification.**
- **Disclosure of a code or other means of re-identifying PHI or de-identified data constitutes disclosure of PHI**

How Much PHI May Be Used or Disclosed? HIPAA's Minimum Necessary Rule

- CE must make reasonable efforts
- When using, *disclosing* or requesting PHI from another CE
  - Sponsors must request/obtain and CEs must disclose only the minimum necessary
- To limit PHI to the minimum necessary to accomplish the intended purpose
  - CE may not use an entire medical record unless it can justify that it is the minimum necessary
- Exception: Does *not* apply to uses or disclosures pursuant to an authorization

What is *Not* PHI?

- Tissue (but may become PHI, e.g. genetic analysis)
- De-identified data

"De-identified" Data

- **Methods:**
  - **Safe harbor: 18 direct identifiers are removed, or**
  - **Statistically de-identified**
- **And covered entity has *no actual knowledge* that the individual can be re-identified**

Safe Harbor De-identification: Remove 18 Direct Identifiers

- Names and ages > 89 *yrs* (but *can* express in months, days, hrs)
- All dates (except year) directly related to an individual
- Addresses: geographic subdivisions smaller than a state, email, URLs, WWW, internet protocol address
- Numbers: telephone, and fax, social security, medical record, health plan, account, certificate/license numbers
- Vehicle or device identifiers and serial numbers
- Biometric identifiers (finger,voice prints), full face photos
- Any other unique identifying number, characteristic, or derived code (catchall)

Something In Between PHI and De-identified Data: Limited Data Sets

- Created in final Privacy Rule in response to research community
- Excludes 15/18 direct 'safe harbor' identifiers
- Includes some PHI:
  - Dates (birth, death, admission, discharge)
  - Addresses (town/city, state, 5 digit zip code) *except* street address
  - Re-identification code

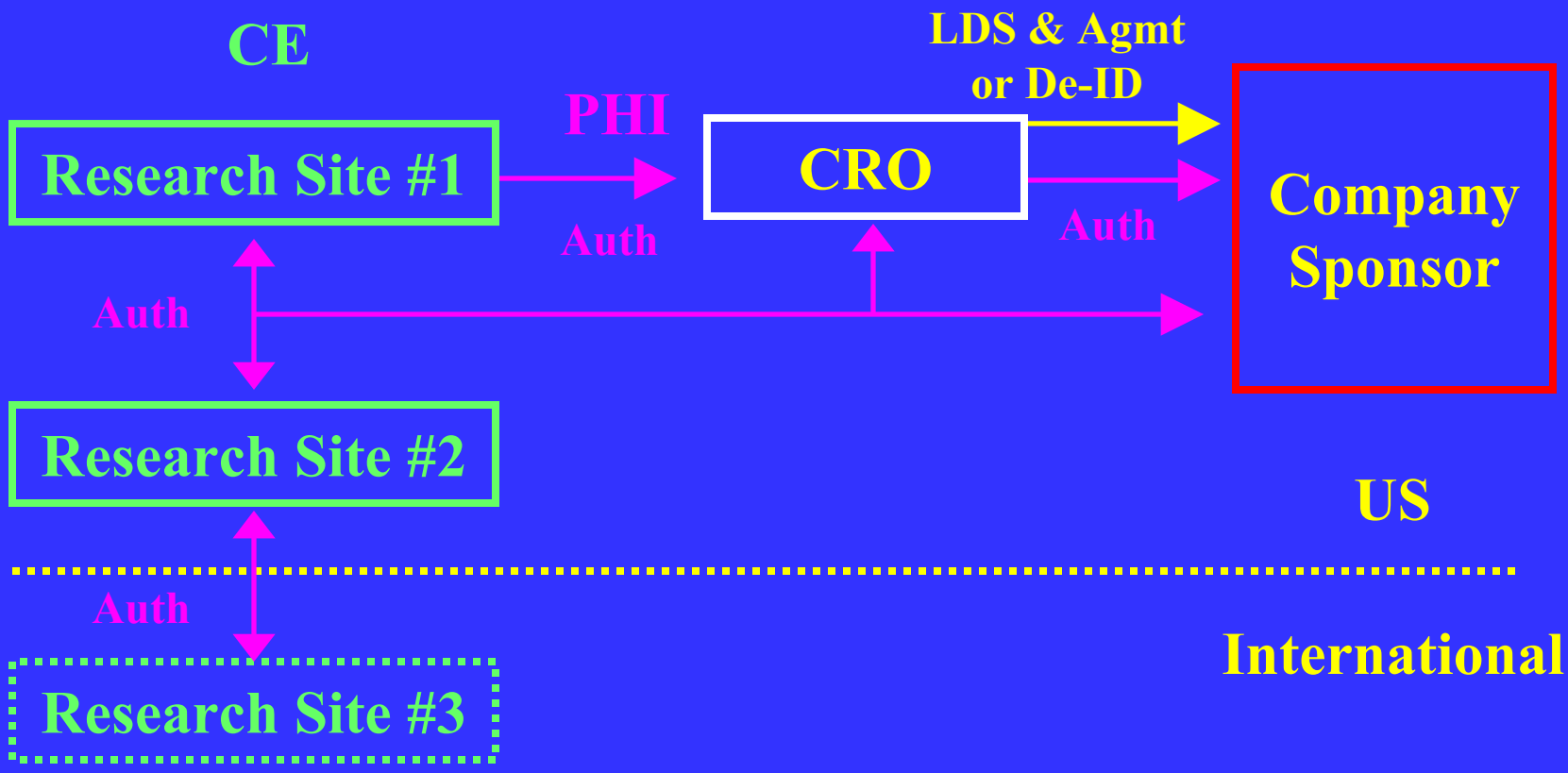
Use and Disclosure of Limited Data Set

- Authorization *not* required by covered entity:
  - To use LDS for research, public health or health care operations
  - To use PHI to create LDS
- Disclosure to third party requires a data use agreement
  - Minimum necessary rule applies

Disclosure of Limited Data Set: Data Use Agreements

- Permitted uses (research, public health, HCO)
- Who is permitted to use or receive the LDS
- Recipient responsibilities:
  - To *not* use LDS to <u>contact</u> individuals (may not use for recruitment) or identify the information to others
  - Report to CE unpermitted uses/disclosures of "which it is aware"
  - Use appropriate safeguards to comply with data use agreement
  - Ensure downstream compliance with agents & subcontractors

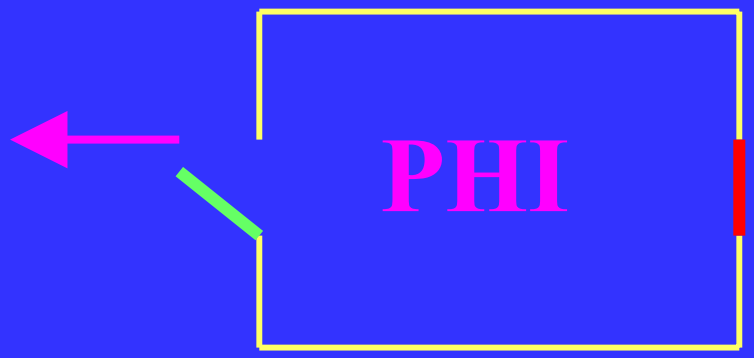
Disclosure of PHI by the Covered Entity – Follow the PHI



Research + CE + PHI = Authorization

HIPAA Authorizations = Default Rule

- Treatment
- Payment
- Health Care Operations



Research

- Default: door to PHI for research is *closed*
- To access or obtain PHI for research, sponsor must use a HIPAA mechanism to *open* the door

Revocations of Authorization

- Subjects have the right to revoke authorization at any time
- Must request in writing
- Unless the covered entity has acted "in reliance on" authorization
  - CE *may* continue to use/analyze PHI collected before the revocation (= minimal risk to subject)
  - CE may *not* continue to disclose PHI unless necessary to preserve the integrity of the study
    - Permitted disclosures: FDA, AEs, notify sponsor of withdrawal, investigate scientific misconduct

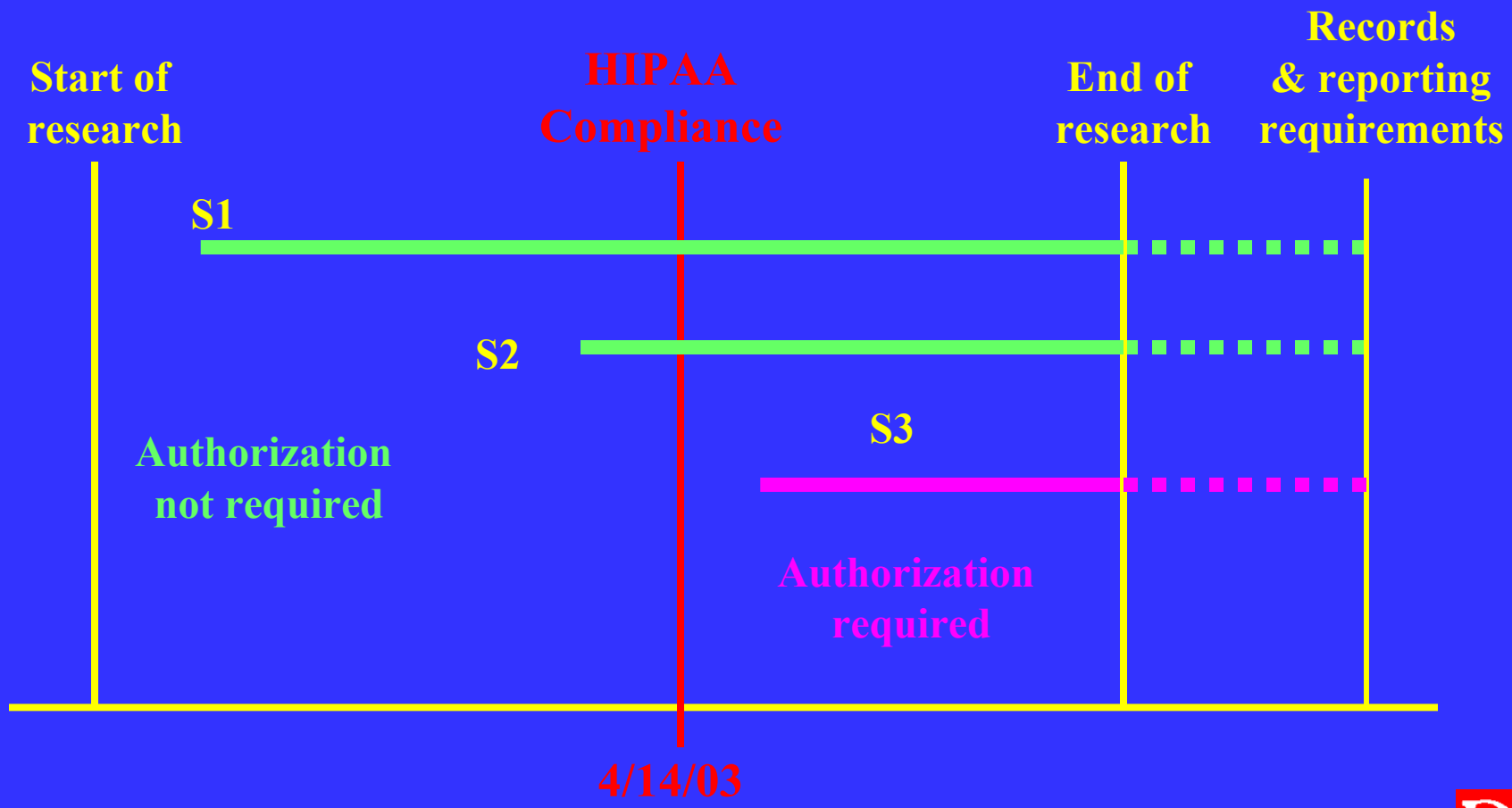
When is an Authorization *Not* Required?

- Limited data set
- Grandfathered authorization (on-going study)
- Research on PHI from decedents
- Reviews preparatory to research
- Research qualifies for a waiver of authorization
- Disclosure is permitted under HIPAA
- Disclosure to a business associate

HIPAA's 'Grandfather' Provisions For On-going Research

- Covered entity may use/disclose PHI
- That it created or received before or *after* the HIPAA compliance date (4/14/03)
- For a research study
- IF the covered entity obtained either
  - Informed consent,
  - IRB-approved waiver of informed consent, or
  - Express legal permission
- *Before* the compliance date
- Applies to PHI entered in databases prior to April 14, 2003

Application of HIPAA's Grandfather Provisions



Disclosures of Decedent's PHI

- CE may disclose PHI from deceased persons to an outside researcher
- IF the CE obtains a "representation" (notice) from the researcher that:
  - PHI is to be used solely for research, and
  - The PHI is necessary for the research purpose
- Researcher must provide documentation of death if requested by CE

Reviews Preparatory to Research

- CE may disclose PHI to an outside researcher (sponsor, CRO, collaborator)
- IF the CE obtains a "representation" (notice) from the researcher that:
  - PHI is to be reviewed solely "to prepare a research protocol or for a similar purpose" (preparatory to research), and
  - The PHI is necessary for the research purpose
- PHI may not be removed from the covered entity's site
  - No remote access (prohibits electronic transfer of PHI)

Use of 'Reviews Preparatory to Research' by Sponsors

- Feasibility analysis
- Protocol development
  - PHI is to be used solely "to prepare a research protocol or for a similar purpose" (preparatory to research), and
  - The PHI is necessary for the research purpose
- Screening subjects
  - Note: physicians may *use* their patients' PHI to screen subjects w/o authorization under 21 CFR 164.502(a)(1)(i)
- PHI may *not* be used to contact/recruit subjects

Waivers or Alterations of Authorizations: Criteria

1. **The use/disclosure of PHI involves *no more than <u>minimal</u> risk* to the PRIVACY of the subject**
   - **Adequate plan to *protect the identifiers* from improper use and disclosure,**
   - **Adequate plan to *destroy the identifiers* at the earliest opportunity, and**
   - **Adequate written assurances that *PHI will not be reused or disclosed* except as permitted under HIPAA**

Criteria for Waivers or Alterations of Authorizations - Cont'd

2. The research could not practicably be conducted <u>without the alteration or waiver</u>
   - Would not apply if research involves subject interaction
3. The research could not practicably be conducted <u>without access to and use of PHI</u>
   - Is PHI really necessary?

Waiver or Alteration of Authorization Requirements For Research

- Who must approve the waiver/alteration?
  - Institutional Review Board (IRB), or
  - Privacy board
- Waiver or alteration must be requested and approval documented in writing

How Will Waivers Be Used in Research?

- Re-analysis of PHI in a new study
- Use PHI only to recruit/contact prospective subjects
- Waive a required element of the authorization
  - Sensitive studies in which subjects do not want to sign an authorization (e.g., drug use)

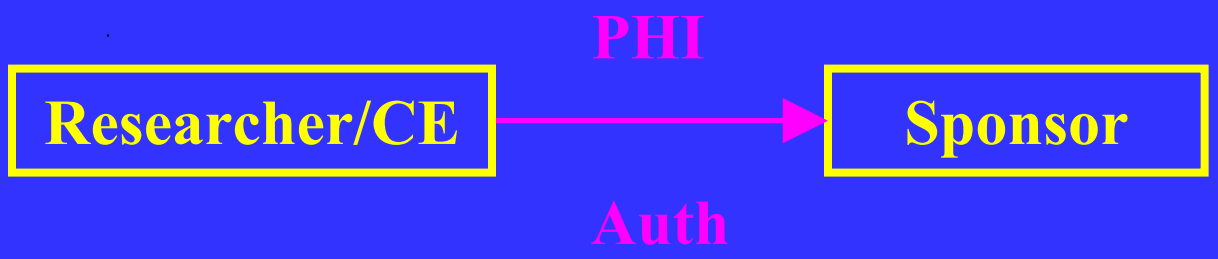
Permitted Public Health Disclosures Under HIPAA: FDA Reporting

- CEs may disclose PHI w/o authorization to:
  - Persons subject to FDA jurisdiction
  - "Person" includes companies (sponsors)
- With respect to an FDA-regulated product
- Regarding the safety, effectiveness or quality of the product
  - Includes: Adverse events, device tracking, product recalls, lookbacks, post-marketing surveillance
  - Excludes: marketing
- Minimum necessary applies

Disclosures to Business Associates

- CE may disclose PHI to a business associate w/o authorization
- Who is a "business associate"?
  - A third party that uses the CE's PHI
  - To perform a function or service *on behalf of* the covered entity
  - Must have a written business associate contract with the CE
- Are sponsors of research "business associates"?

Are Sponsors of Research Business Associates?



Answer: No. Disclosure of PHI by a CE to a sponsor for research purposes does NOT create a business associate relationship and does not require a business associate contract. BUT, must comply with authorization requirements.

Source: Office of Civil Rights, Guidance on HIPAA's Privacy Rule, December 4, 2002, http://www.hhs.gov/ocr/hipaa/guidelines/businessassociates.wpd.

Tracking Disclosures

- HIPAA provides a right to individuals for an accounting of all disclosures of their PHI by a CE for the previous 6 years
- CEs must track all disclosures of PHI
- Exception: Does *not* apply to disclosures made under
  - An authorization
  - A data use agreement (disclosure of LDS)
- Applies to:
  - Reviews preparatory to research
  - Waivers
  - Disclosures to and by business associates

How Will HIPAA Affect Sponsors?

1. Subject screening
   - No subject contact
   - By the CE
   - By outside researcher
2. Subject recruitment
   - Subject contact
   - Targeted contacts – needs PHI
   - Non-targeted advertising – does not need PHI

Mechanisms For Subject Screening

1. Reviews preparatory to research
   - Need representation/notice from researcher
   - PHI may not be removed from site
2. Limited data sets
   - Covered entity may *disclose* LDS with data use agreement

- PHI may *not* be used by 3P to contact subjects with either mechanism

Reviews Preparatory to Research: May *Not* be Used to Recruit Subjects

NPRM, March 2002:

"Commenters expressed concern and confusion as to how researchers would be able to recruit research subjects when the Privacy Rule does not permit [PHI] to be removed from the covered entity's premises during reviews preparatory to research."

"The Department clarifies that the Privacy Rule's provisions for IRB or Privacy Board waiver of authorization are intended to encompass a partial waiver of authorization for the purposes of allowing a researcher to obtain [PHI] necessary to recruit potential research participants."

Reviews Preparatory to Research: May *Not* be Used to Recruit Subjects

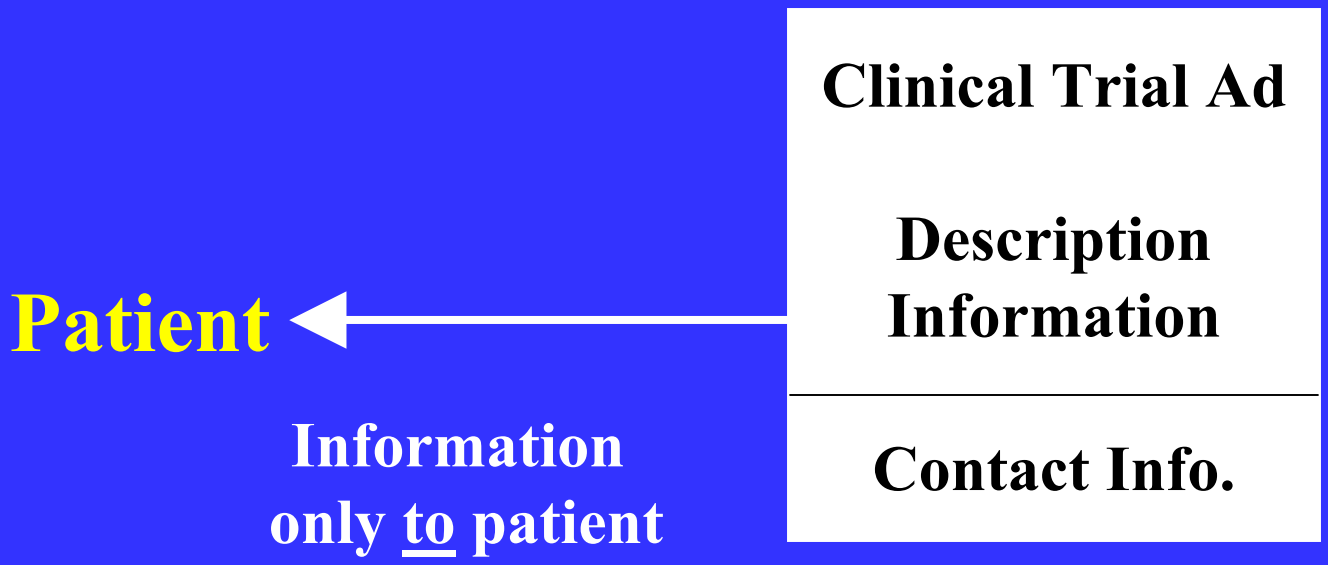
NPRM, March 2002:

"For example, even if an IRB does not waive informed consent and individual authorization for the study itself, it may waive such authorization to permit the disclosure of protected health information to a researcher as necessary for the researcher to be able to contact and recruit individuals as potential research subjects."

Subject Recruitment/Contact

- May *not* use LDS to contact subjects
- May *not* do under "Reviews Preparatory to Research" exception (not protocol development)
- Must either have:
  - Authorization (e.g., obtained in previous study), or
  - Waiver of authorization
    - Waiver for subject recruitment = "partial waiver" of authorization (preamble to NPRM)

Subject Recruitment: General 'Passive' Advertising



Subject Recruitment: General 'Interactive' Advertising

Is source a covered entity?

Is recipient a covered entity?

Patient or Physician

PHI?

Clinical Trial Website

Description Information

Patient Information (Name, phone, email, other)
Cookies/Clickstream data
DoubleClick Info/3Ps

Impact of HIPAA On Sponsors

- New procedures - revise protocols
  - Feasibility studies and subject screening
  - Subject recruitment
    - Partial waivers - IRB/privacy board review and approval
    - Protocol revisions - recruitment and enrollment
  - Voluntary databases and registries - need authorizations to use for research
    - Expiration date = “none”
- Revise informed consent form to add authorization elements
  - Use CE’s authorization forms?

Impact of HIPAA On Sponsors

- Revise clinical trial agreements to include HIPAA compliance (with CE, with CROs)
- Monitoring visits and detail reps – need authorizations if PHI is disclosed
- Multi-site studies
  - State preemption analyses
    - HIPAA does not preempt more protective state laws (Texas, California)
  - Coordination with international privacy laws
    - E.U. Data Directive
    - Non-E.U. countries
- Exposure to liability – risk assessment

Privacy Rule Compliance Deadline

April 14, 2003

(40 days!)

Are you and your research partners ready?

HIPAA Websites

- http://www.aspe.hhs.hhs.gov/admnsimp
- http://www.hhs.gov/ocr/hipaa
- http://www.aamc.org/members/gir/gasp
- http://www.healthlawyers.org
- http://www.wedi.org/snip
- http://dwtnet/intranet/practicegroups/healthlaw/privacylinks.asp

R & D Privacy Issues for Pharmaceutical Manufacturers

Questions?