
HIPAA: Is Your Institution In Compliance?

NCURA Annual Meeting
November 4, 2003

State University of New York



HIPAA: A Large Undertaking – But Not Impossible, Even for Complex Academic Enterprises

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State University of New York
System Administration



Agenda

- SUNY & Research Foundation
 - Size
 - Corporate Structure
- Overview – “Generic HIPAA In a Academic & Research Environment”
- Project Assignment
- Project Planning
- Execution & Deliverables
- April 14, 2003 - But not the end

State University of New York

- State Agency with separate corporate structure
- 64 campuses divided into four categories based upon educational mission
 - University center/doctoral degree granting
 - Comprehensive four year college
 - Technology college
 - Community college
- 403,000 students

THE STATE UNIVERSITY of NEW YORK Complete Campus Listing



Research Foundation

- Private, non-profit educational corporation
- Administration of externally funded contracts & grants for and on behalf of SUNY
- Provides independence and administrative flexibility for special demands of sponsored research
- Hybrid Entity: self-insured, self-administered health plan
- Business Associate of SUNY
- FY 03 expenditures of \$630 million

HIPAA: Health Insurance Portability and Accountability Act – 1996

P.L. 104 – 191

(a.k.a. Kennedy-Kazenbaum)

■ Intention

- Assure portability of health insurance
- Decrease healthcare fraud and abuse
- Improve efficiency and effectiveness of healthcare
- Enforce standards
- Guarantee Privacy and Security of Individually Identifiable Health Information (IIHI)

Protected Health Information

45 CFR 160.103, 160.501

- Protected Health Information (“PHI”) is IHI in any form (oral or recorded) that is:
 - Created or received by a covered entity; and
 - Related to the past, present, or future physical or mental health of an individual; the provision of health care to an individual; or the payment for the provision of health care to an individual; and
 - Either identifies the individual or is reasonably likely to allow identification of the individual

Individually Identifiable Data Elements

- Names
- Geographic subdivisions smaller than a state (see rule for details concerning use of zip codes)
- Dates of birth, admission, discharge, and death
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical Record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers (e.g., of healthcare professionals)
- Vehicle identifiers
- Device identifiers (e.g. of pacemakers)
- URLs
- IP addresses
- Biometric identifiers
- Full face photographs
- Any other unique identifying number, characteristic, or code (e.g. blue-eyed, blond oriental who is 7 feet tall)

HIPAA'S Component Parts

Standard	Final Rule Publication	Compliance Date
Transactions & Code Sets	8/17/00	10/16/02 (extension granted to 10/16/03 if requested)
National Provider Identifier	TBA	24 months following effective date
National Employer Identifier	TBA	24 months after effective date
Privacy	12/28/00	4/14/03
Security	4/20/03	4/20/05

The Theory Behind HIPAA

“An individual’s rights and welfare must never be sacrificed for scientific or medical progress”

Comments to proposed HIPAA standards
page 974 Edward B. Goldman, J.D.

Who Is Covered?

45 CFR 160.103

- The following are considered covered entities
 - Health plan
 - Healthcare clearinghouse
 - Healthcare provider who transmits any health information in electronic form in connection with a standard transaction



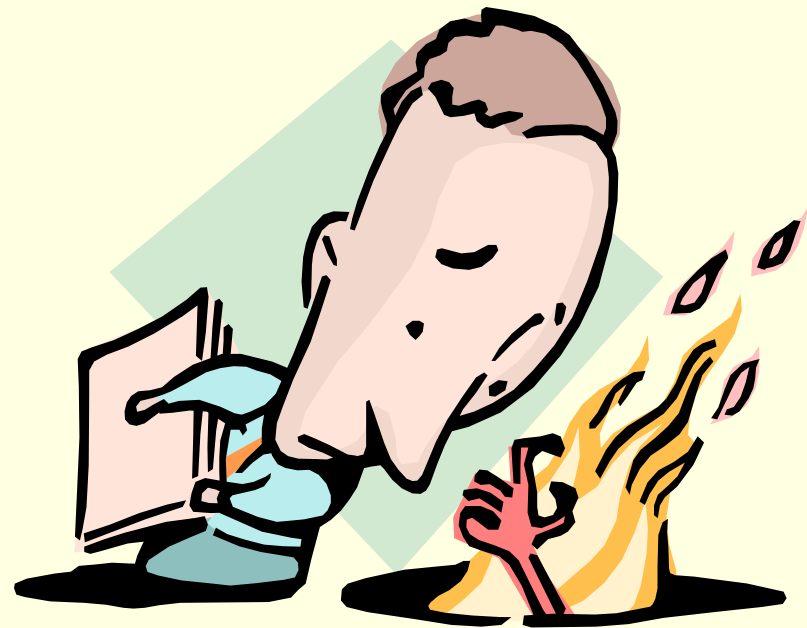
Standard Transaction

45 CFR 160.103

- The standard transactions are:
 - Health care claims
 - Health care payments & remittance advice
 - Coordination of benefits
 - Health care claim status
 - Enrollment & disenrollment in a health plan
 - Eligibility for a health plan
 - Health plan premium payments
 - Referral certification & authorization
 - First report of injury
 - Health claims attachments
 - Other transactions as prescribed by DHHS Secretary

Project Assignment

- Implement and comply with the unfunded federal mandate using existing resources
 - Unfunded obligation for University and campuses to also absorb cost of compliance
- Do not create an expectation by campuses that the State is in the position to provide additional budget support
- Meet compliance deadline
- In other words, business as normal



Project Assignment

(continued)

- Initial confusion concerning HIPAA requirements
- SUNY slow to start
 - Team organization
 - Executive education
 - Scheduling/coordination
 - Funding



Project Planning

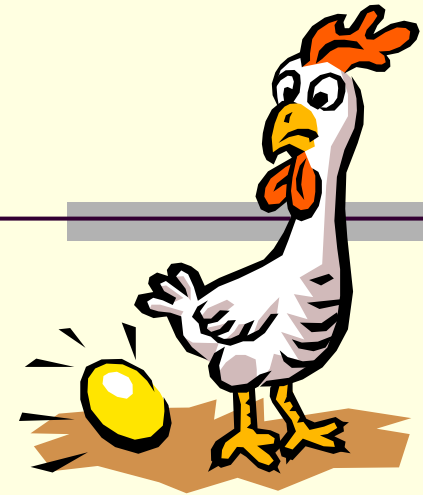
SUNY and RF approach

- Partnership
 - guidance
 - direction
- Development of consistent positions, as legally or operationally permissible
- Consideration of limited financial and personnel resources
 - economies of scale
- Campus flexibility
 - HIPAA implementation is very specific to organizational structure. Failure to consider organizational structure can lead to following guidance that is not applicable to your institution.
- Sharing of information and positions endorsed
- Shared compliance program based on self assessment

Project Planning

(continued)

- Starting point?
 - Who is the covered entity?
 - SUNY - hybrid entity
 - Principle role is academics, however a number of covered functions exist on campuses that maybe subject to HIPAA standards, based upon operational attributes
 - Additional Considerations
 - Covered Entities are not the only players affected
 - “Business Associates” , non-employees who perform a service for the covered entity and have access to personal health information
 - Lawyers, actuaries, collection agencies, medical transcriptionist, consultants, vendors
Research Foundation



Project Planning

(continued)

Impact on University

- Hospitals, Clinics
- Practice Plans
- Non-medical practice activities
- Research
- Counseling Centers
- Educational Opportunity Centers
- Student Health Clinics (based on operational characteristics)
- Student Health Insurance (international students)
- Athletics
- Academic Programs
- Affiliations & Internships

Campus

		HIPAA Compliance Strongly Recommended	
		<p>Not Protected Health Information (Not Legally Subject to HIPAA)</p> <ul style="list-style-type: none"> • Athletic Training • Student Health • Human Subject Research (collecting health information) 	<p>Not Covered by HIPAA</p> <ul style="list-style-type: none"> • Research Functions (not using personal health information) • Teaching Activities • Building and Grounds • NYS Education Department Projects <ul style="list-style-type: none"> ➢ CSTEP ➢ STEP
Conduct One of the Standard Transactions?	No		
	Yes	<p>Protected Health Information (Covered by HIPAA)</p> <ul style="list-style-type: none"> • Speech and Hearing • Traumatic Brain Injury • Alzheimer's Program • Administration of Self-Insured Health Plan • Study requiring chart review of PHI held at affiliated hospital 	<p>Not Covered by HIPAA</p> <ul style="list-style-type: none"> • Self-Insured enrollment functions
		<p>Required to comply with the requirements of HIPAA</p>	
		Yes	No
		Individually Identifiable Health Information?	

Not Required to Comply with HIPAA

RESEARCH

		HIPAA Compliance Strongly Recommended	
		<p>Not Protected Health Information (Not Legally Subject to HIPAA)</p> <ul style="list-style-type: none"> • A Clinical Evaluation of a Powered Dental Flosser (Buffalo) • Clinical Analysis of Connective Tissue & Free Gingival Grafts in Smokers vs. Non-Smokers (Buffalo) 	<p>Not Covered by HIPAA</p> <ul style="list-style-type: none"> • Adaptation to Nonnative Speech by Human & Computer (Buffalo) • Habituation to Food in Children (Buffalo)
Conduct One of the Standard Electronic Transactions?	No		
	Yes	<p>Protected Health Information (Covered by HIPAA)</p> <ul style="list-style-type: none"> • Zimmer-LPS Flex Mobile Bearing Knee Study (Upstate) • Study of the Efficacy, Safety, and Immunogenicity of Rota Teq at Expiry Potency (Upstate) 	<p>Not Covered by HIPAA</p> <ul style="list-style-type: none"> • Retrospective Review on Pet Scans In Head & Neck Cancer Patients (Upstate) • PPD Conversion Rates in Hospital Employees (Upstate)
		Required to comply with the requirements of HIPAA	
		Yes	No
		Individually Identifiable Health Information?	

Not Required to Comply with HIPAA

Project Planning

(continued)

- Approach
 - Education
 - In-house/consultant
 - Resource availability
 - Timing
 - Buy-in

SUNY's Compliance Process

- ❑ Consulting Engagement
 1. Education and Awareness Training
 2. Impact Assessment (Readiness Assessment)
 3. Implementation Planning
 4. Implementation
 5. Training, Management & Enforcement
 6. Audit
- ❑ "Six City" Training Program
 - January / February 2003
 - Educational Program
 - Toolkit
 - Recommended approach and methods
 - 63/64 (98.4%)



Execution & Deliverables

- Awareness training & education
 - Impact analysis
 - Identify gaps
 - Analyze gaps to assess impact and risks
 - Implementation Planning
 - Prioritize remediation efforts based on risks and time frame for implementation
 - Identify costs to achieve implementation
 - Transaction & Code Sets
 - Security
 - Audit and compliance
- Future**

HIPAA Research Compliance: Putting Privacy into Practice

Cynthia Nappa
Institutional Privacy Administrator
State University of New York
Upstate Medical University



Agenda

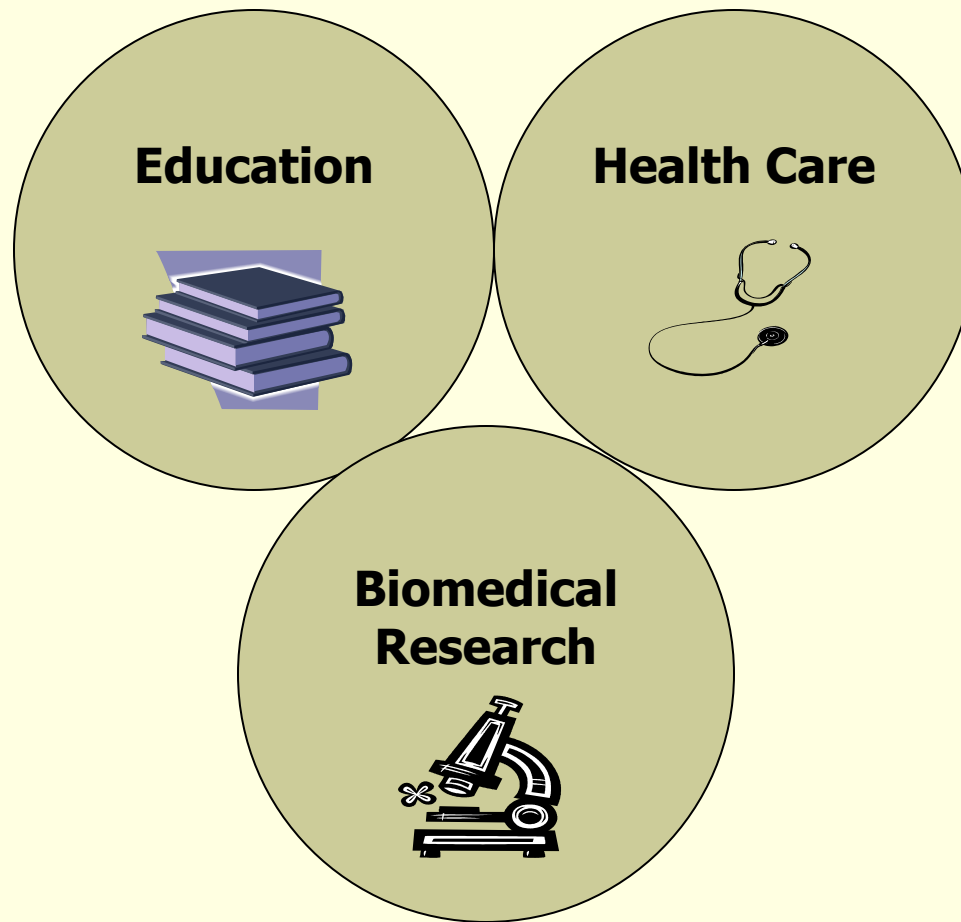
- **SUNY Upstate Medical University**
 - Composition and Size
 - Research Focus Areas
- **Overview of Research as a Covered Function**
 - Analysis of Research 'Fit' Within the Organization
 - Health Care Component Determination
- **Mechanisms to 'unlock the door to PHI'**
- **IRB and Privacy Board Functions**
- **Gaining Access to Patient Data**
- **Monitoring and Oversight**
- **Adverse Outcomes?**

SUNY Upstate Medical University

- Regional Academic Medical Center in downtown Syracuse; one of four medical universities in SUNY System
 - Four Colleges
 - College of Medicine
 - College of Health Professions
 - College of Nursing
 - College of Graduate Studies
 - University Hospital
 - 350 beds and multiple ambulatory care locations
 - Level 1 Trauma Center
 - Serves 15 counties
 - More than 300,000 patients treated yearly

Tripartite Mission of SUNY Upstate

Improving the health of the communities we serve through



Clinical Research Areas Of Focus

- Major focus of Research activity is organized into four multidisciplinary areas:
 - Cancer
 - Cardiovascular Science
 - Neurosciences
 - Human Performance
 - \$50 million Institute for Human Performance opened in January 2000

The HIPAA Privacy Rule:

“Administrative Simplification”?

Misinterpretation of the requirements may constitute reasonable cause if evidence of due diligence can be demonstrated. Misinterpretation without due diligence, however, may not constitute reasonable cause...

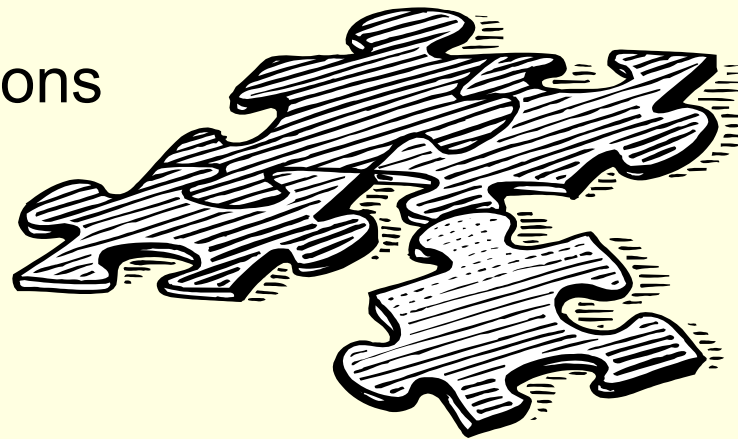
“No Civil Monetary Penalties if failure to comply is due to reasonable cause and not willful neglect”

HHS/OCR 42 USC § 1320d-5

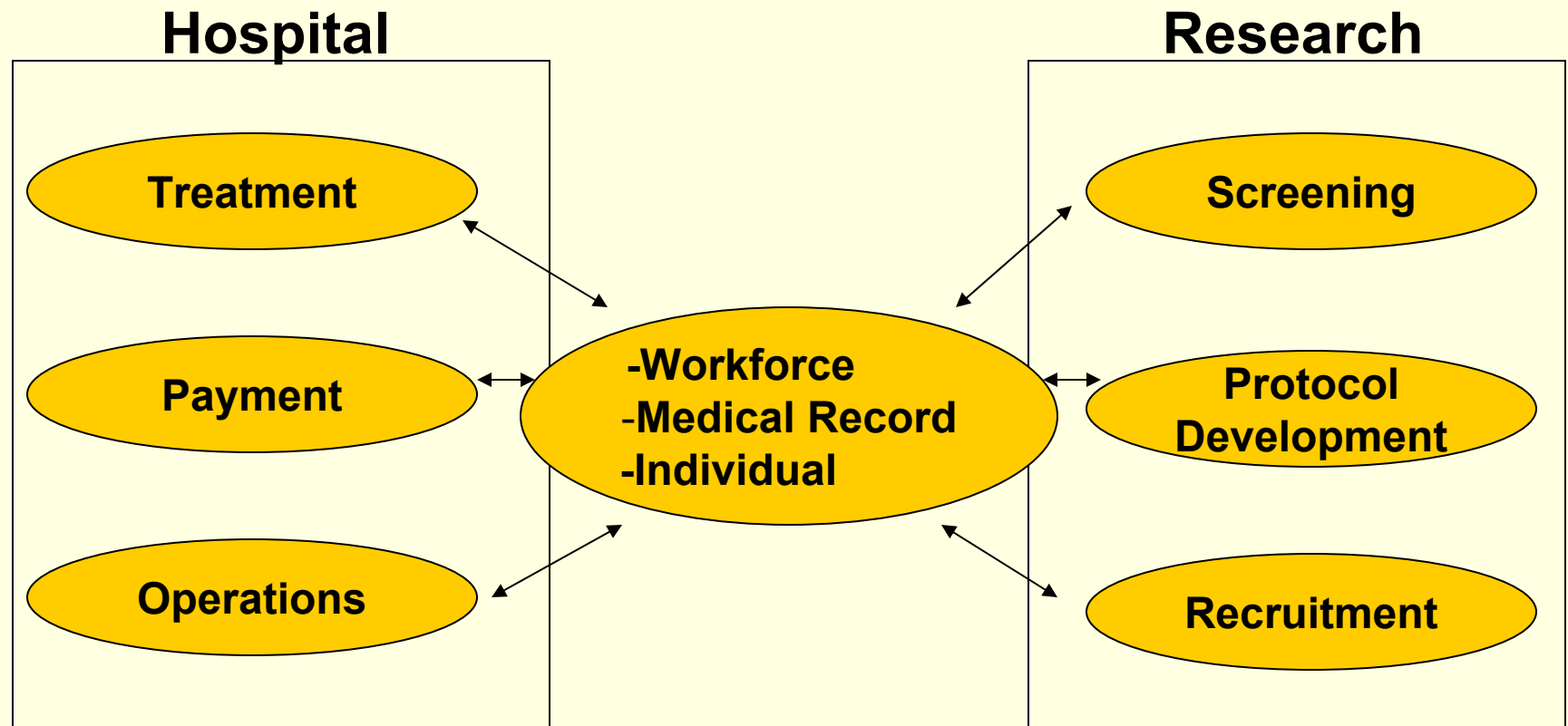


Where Does Research Fit at SUNY Upstate?

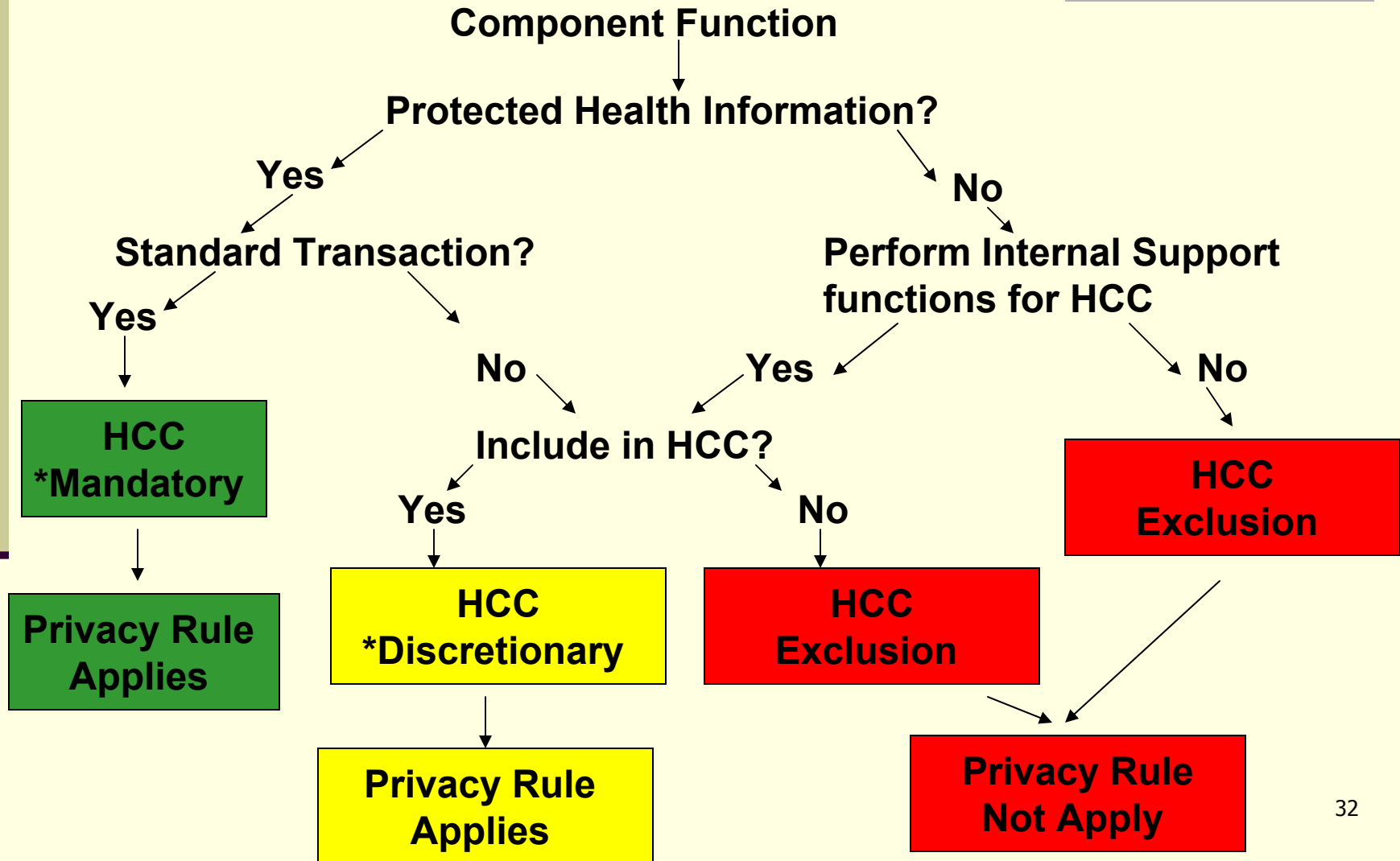
1. Clinical Research may Involve Treatment
2. Co-Mingling of Research and Treatment Information
3. Dual Role of Providers: Health Care and Research
4. Research Supports Mission of Academic Medical Center
5. Consumer Expectations



Recognizing The Overlap at SUNY Upstate...



HEALTHCARE COMPONENT ANALYSIS AT SUNY UPSTATE



SUNY UPSTATE MEDICAL UNIVERSITY HIPAA Organizational Structure

State University of New York

*Hybrid Covered Entity

Upstate Medical University

* Component of SUNY Hybrid

*Health Care Component

❖ Provider Functions

- Research *
- Education *

•UH

❖ Business Functions

- Univ. Counsel
- Public Safety
- Institut. Compliance
- Diversity Aff. Action
- Emp/Labor Relations
- Public/Media Relations
- Internal Audit
- IMT
- Executive Council

*Non Health Care Components

*Organized Health Care Arrangement

- ❖ Faculty Providers (Full-time & Volunteers)

PHI ↔

PHI ↓

*Business Associate Relationships

MSG

RF

Other Vendors

Firewall

*Involving IIHI of University Hospital

SUNY Upstate - Research Studies Involving Access, Use, Disclosure Of IIHI

<p>352 IRB Approved Studies Involving IIHI</p> <p>23 IRB Approved Studies Issued an Exemption</p> <p>3 IRB Approved Studies Using Limited Data Sets</p> <p>100 IRB Approved Studies Under Transition Provision</p>	<p>25 IRB Approved Studies Not involving IIHI</p>
<p>478 Approved Studies</p>	

Yes

Individually Identifiable Health Information?

No

UNLOCKING THE RESEARCH DOOR TO PHI AT SUNY UPSTATE



Authorization

Waiver of
Authorization

Review Preparatory to
Research

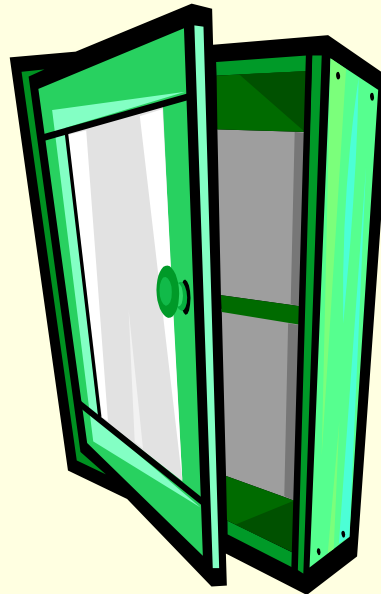
Decedent PHI

Limited Data Set

De-Identification

Transition Provision

RESEARCH

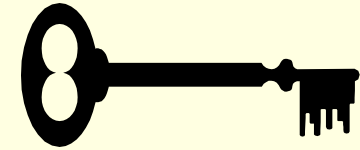


Common Rule vs. Privacy Rule

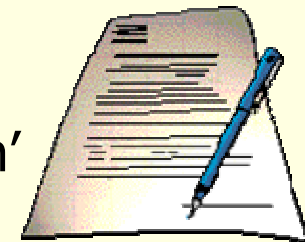
<u>COMMON RULE</u>	<u>PRIVACY RULE</u>
Applies to federally supported or FDA regulated research	Applies to all research
Protects interests and welfare	Protects privacy rights and welfare
Human subject: A living individual about whom an investigator obtains (1) data	Individual: subject of information; a living or deceased person
Institutional Review Boards (IRBs)	Uses IRBs <u>or</u> Privacy Boards
Continuing review at least annually	No requirement for continuing review
Informed Consent	Authorization and Consent
Data recording exempt if done so "in manner that subjects cannot be identified"	Data recording exempt if de-identified



AUTHORIZATION



- “Gold Standard” for disclosure of PHI
- Written in plain language 8th grade reading level
- Combined with informed consent
- Revocation right balanced with ‘Reliance exception’
- Authorization specific to disclosure required for external research
- Subjects given a *Notice of Privacy Practices*



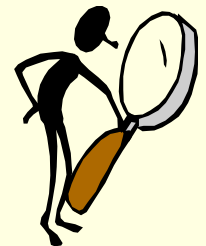
LESSON LEARNED: Beware of “Authorization Avoidance Syndrome”!



WAIVER OF AUTHORIZATION



- The Researcher must complete a *Waiver of Authorization Form*
 - The use or disclosure involves no more than minimal risk to the privacy of the individual
 - The research could not practicably be conducted without the waiver
 - The research could not practicably be conducted without access to and use of the PHI



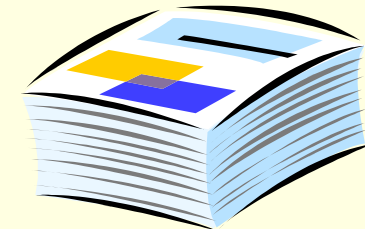
LESSON LEARNED: Be clear on interpretation of “practicably”!



REVIEW PREPARATORY TO RESEARCH



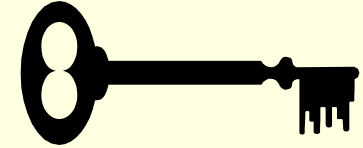
- Researcher must complete a *Review Preparatory to Research Request Form*
 - The PHI will be used solely to prepare a research protocol or similar purpose
 - The PHI is necessary for the research
 - The PHI is not to be recorded by the researcher
 - The review may only be performed by SUNY Upstate workforce members



LESSON LEARNED: Does not provide a ticket to ride the research train!



DECEDENT PHI



- Researcher must complete a *Research on Decedents' Information Request Form*
 - The use or disclosure is solely for research
 - The PHI is necessary to conduct the research
 - The individual is a decedent
 - The PHI of living person contained in decedents' records will not be used or disclosed



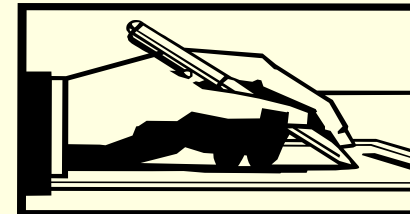
**LESSON LEARNED: In God we trust, all others
bring proof!**



LIMITED DATA SET




- The Researcher must complete a *Limited Data Set Form*



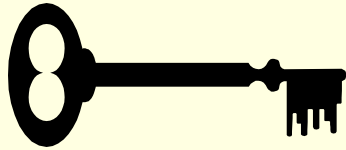
- The data elements must be limited to those that could not be reasonably used to identify the individual
- Disclosures are made pursuant to an execution of a Limited Data Use Agreement
- The request is specific to the study/project

LESSON LEARNED: Don't rely on "what", also ask "what not"!

DE-IDENTIFICATION OF PHI

- Researcher must complete a *De-Identification Certification Form*
 - Removal of ALL 18 identifying elements 
 - The information cannot reasonably identify the individual
 - If statistically de-identify, must provide attestation of qualifications and methodology of statistician

LESSON LEARNED: Be clear – Anonymous and De-identified are not synonymous!



TRANSITION PROVISION



- Permits the use and disclosure of PHI created or received before or after April 14, 2003 if one of the following was obtained prior:
 - Authorization to use and disclose PHI for research
 - Informed consent to participate in research
 - Waiver of informed consent by IRB



**LESSON LEARNED: When Opportunity Knocks
Open the Door!**

WHAT ABOUT RECRUITMENT?

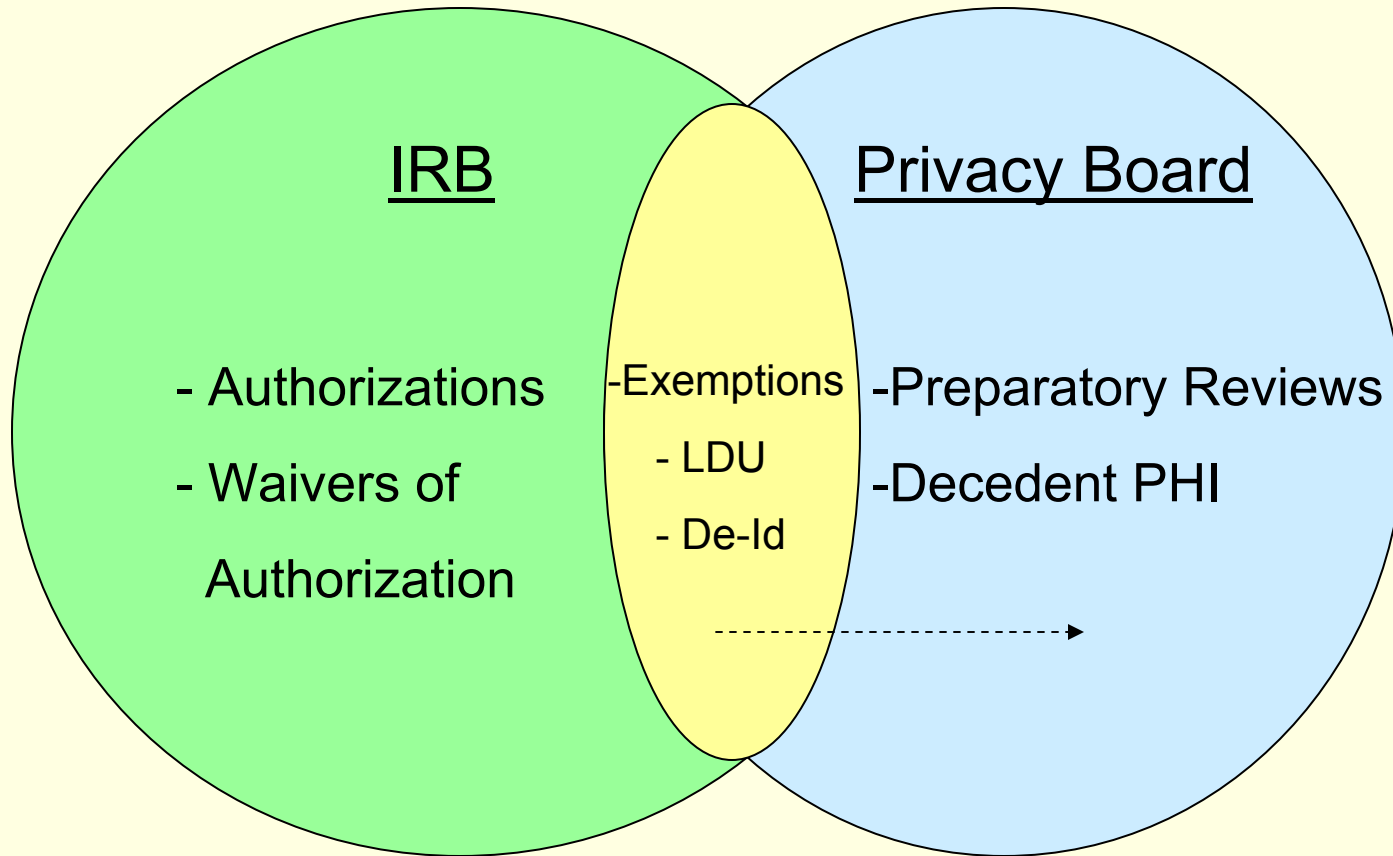


- Treatment provider may discuss with patient
- Patient initiated contact with researcher
- Authorization permitting discussion with researcher
- Waiver of Authorization from IRB permitting discussion with researcher
- Researcher post flyers and advertises

LESSON LEARNED: Be mindful of the 2-headed creature!



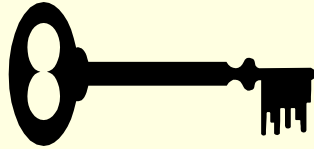
WHO DECIDES?



Human Subject Research

Privacy Oversight & Compliance

WHAT DOES THE PRIVACY RULE REQUIRE?



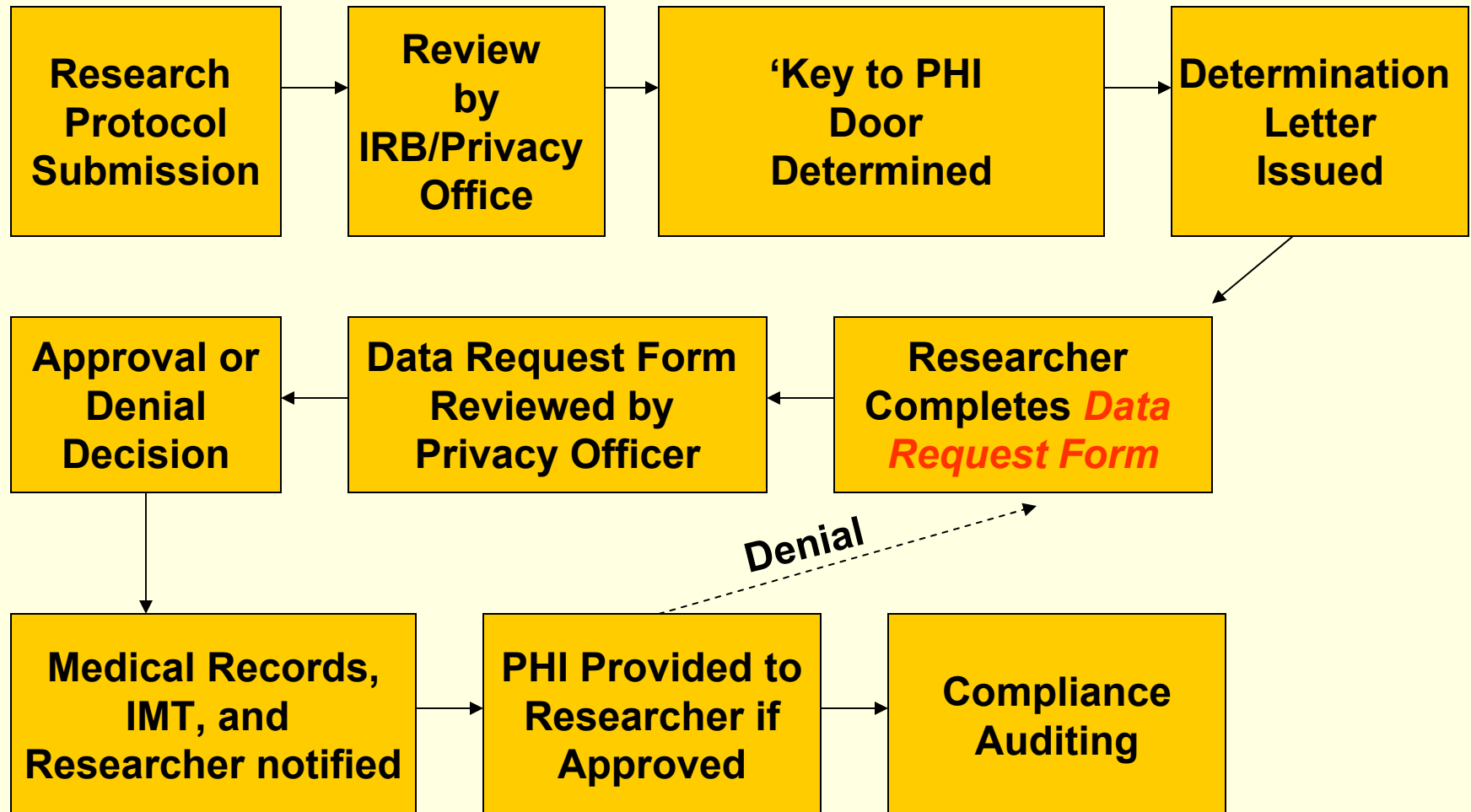
MINIMUM NECESSARY

ACCOUNTING

Authorization	No	No
Waiver of Authorization	Yes	Yes *
Preparatory Reviews	Yes	Yes
Decedent PHI	Yes	Yes
Limited Data Set	Yes	No
De-identification	No	No

* *Modified Accounting for Research Disclosures Tracking* may be used for studies involving disclosures of 50 or more individuals

SUNY Upstate - Access To Research Data

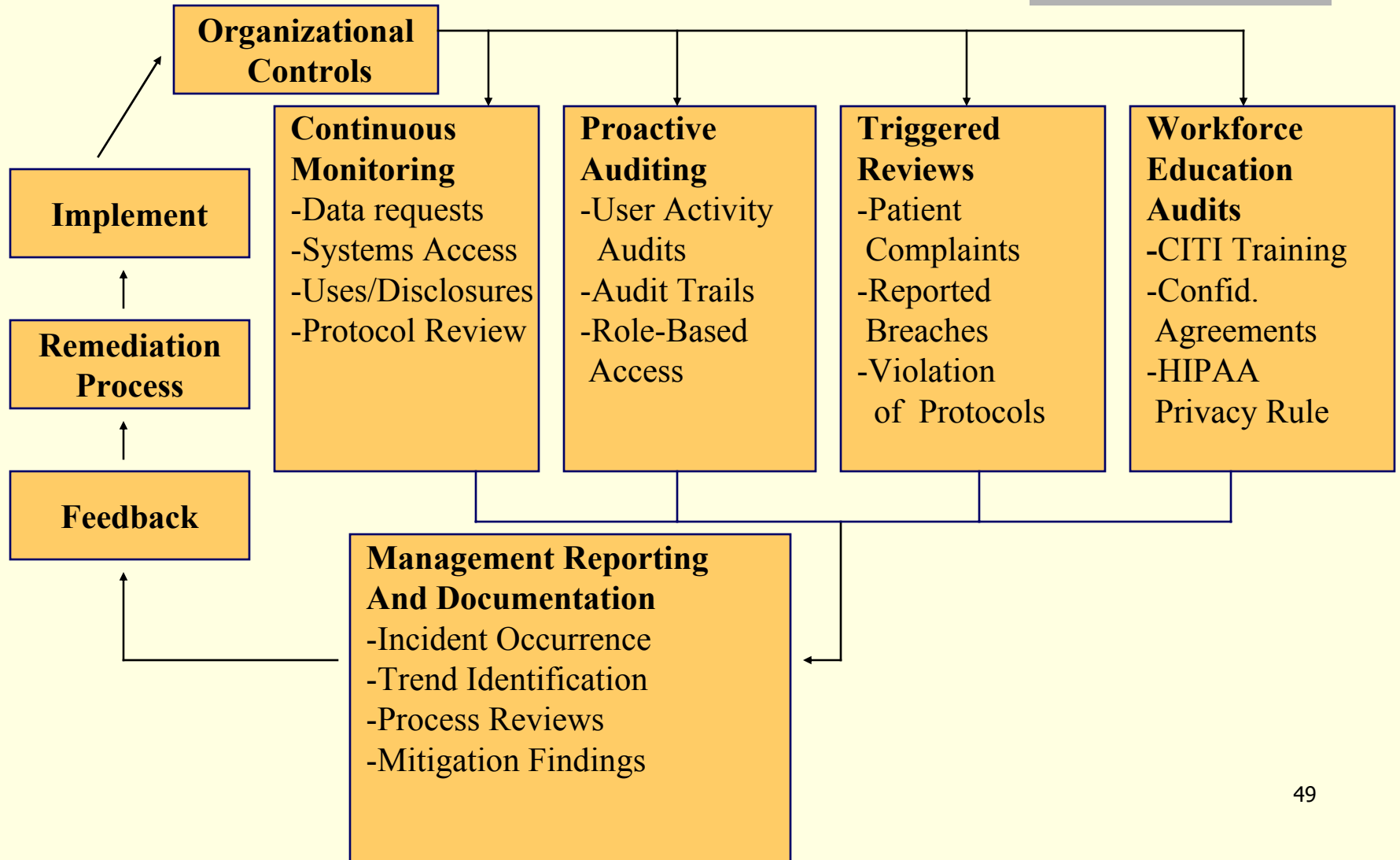


Don't **Surprise** The Patient!

- Receipt of the Notice of Privacy Practices
- Ethical Recruitment Practices
- Permitted Use and Disclosure of PHI
- Accounting of Disclosures



SUNY Upstate - Monitoring & Oversight



What Are Potential Adverse Outcomes?

- Violate Individual's Right to Privacy

- Loss of Public Trust

- Professional Misconduct

[New York State Education Law § 6530(23)]

- Sanctions

- Suspension of Research Activities



Privacy and Research:

A Balancing Act



“Covered entities [should] be mindful of the often highly sensitive nature of research information and the impact of individuals’ privacy concerns on their willingness to participate in research.”

Standards for the Privacy of Individually Identifiable Health Information;
Final Rule (Privacy Rule), 65 F.R. at 82520, December 28, 2000

HIPAA: Impact on Day to Day Administration

Brian Murphy, MS
Director of HIPAA Compliance
State University of New York
University at Buffalo



Agenda

University at Buffalo & HIPAA

- Defining the UB Hybrid Entity Structure
- Determining UB Covered Functions / Research
- Implementing PHI Release to UB Research
- Identifying Common Research Problems
- Solving Problems via Thought-Provoking Scenarios

SUNY University at Buffalo (UB)

- Largest institution in SUNY system
 - 17,290 Undergraduate
 - 8,548 Graduate / Professional
 - 14 Schools & Colleges
- Health Sciences & related schools
 - School of Medicine and Biomedical Sciences
 - School of Dental Medicine
 - School of Nursing
 - School of Pharmacy and Pharmaceutical Sciences
 - School of Public Health and Health Professions
 - School of Social Work
- **NO UB HOSPITAL**
 - >9 partnered (but independent) local teaching hospitals

UB Covered Function Determination

- UB required to designate its SUNY Hybrid Entity covered function components
 - Health Plan: Not Applicable
 - Health Care Clearinghouse: Not Applicable
 - Health Care Component
 - Providers ... ?
 - Research ... ?

UB Covered Function Determination

Who does what for whom?

- SUNY/UB employs faculty, not health care providers
 - Exceptions to this are school of Dental Medicine and Student Health services
- Independent corporate entities employ health care providers, not faculty
 - 21 independent medical/dental practice plans
 - Partnered teaching hospitals
- Research faculty are employed by multiple entities, but professional obligations to each are distinct and separate

UB Covered Function Determination

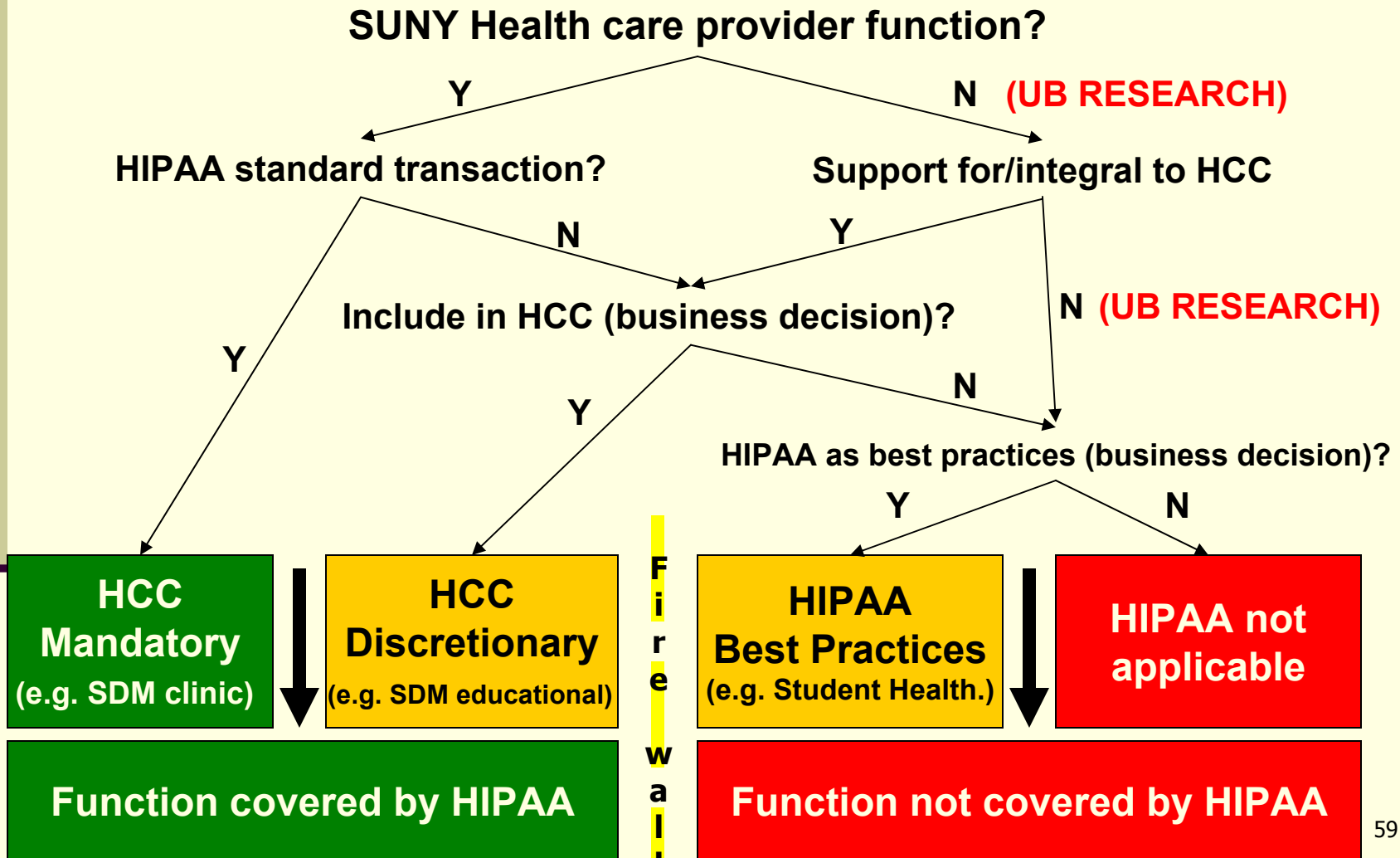
Fitting the reality into HIPAA

- Mechanisms for research access to PHI have little dependence on Covered Entity (CE) status of researcher
 - release of PHI is a “disclosure” instead of a “use”
 - HIPAA, beyond research PHI access mechanisms, does not apply
- External CEs: Health Care Function and Research Function are responsibility of separate legal entities
- Internal UB Covered Functions: 12/2002 OCR “Plain language” guidance on research and CE/non-CE scenarios

UB Health Care Component Designation

- Health Care Component (Covered Function)
 - School of Dental Medicine
 - clinical operations (whether or not they engage in covered electronic transactions)
 - education activities
- UB Research formally declared a non-covered function (not part of Health Care Component) at the institution
- See handouts for formal declarations

UB HEALTH CARE COMPONENT ANALYSIS



SUNY UNIVERSITY AT BUFFALO HIPAA Organizational Structure

State University of New York
Hybrid Covered Entity

University at Buffalo
Component of SUNY Hybrid
Non-Health Care Component
Non-Academic Functions

Academic Functions

- **Research / IRB**
- Provost / Education

- | | | |
|--|---|--|
| <ul style="list-style-type: none"> • RF • University Advancement • Public Service and Urban Affairs • Health Affairs • Internal Audit | <ul style="list-style-type: none"> • CIO / Libraries • Business Office • Facilities • Student Affairs • Athletics • UBF | <ul style="list-style-type: none"> • Media & communications • HR services • Student Associations • EO/AA • Public Safety • Univ. Counsel |
|--|---|--|

***Health Care Components**
Dental Medicine (clinic, education)

Best Practices
voluntary compliance
Student Health

PHI

Firewall

UB

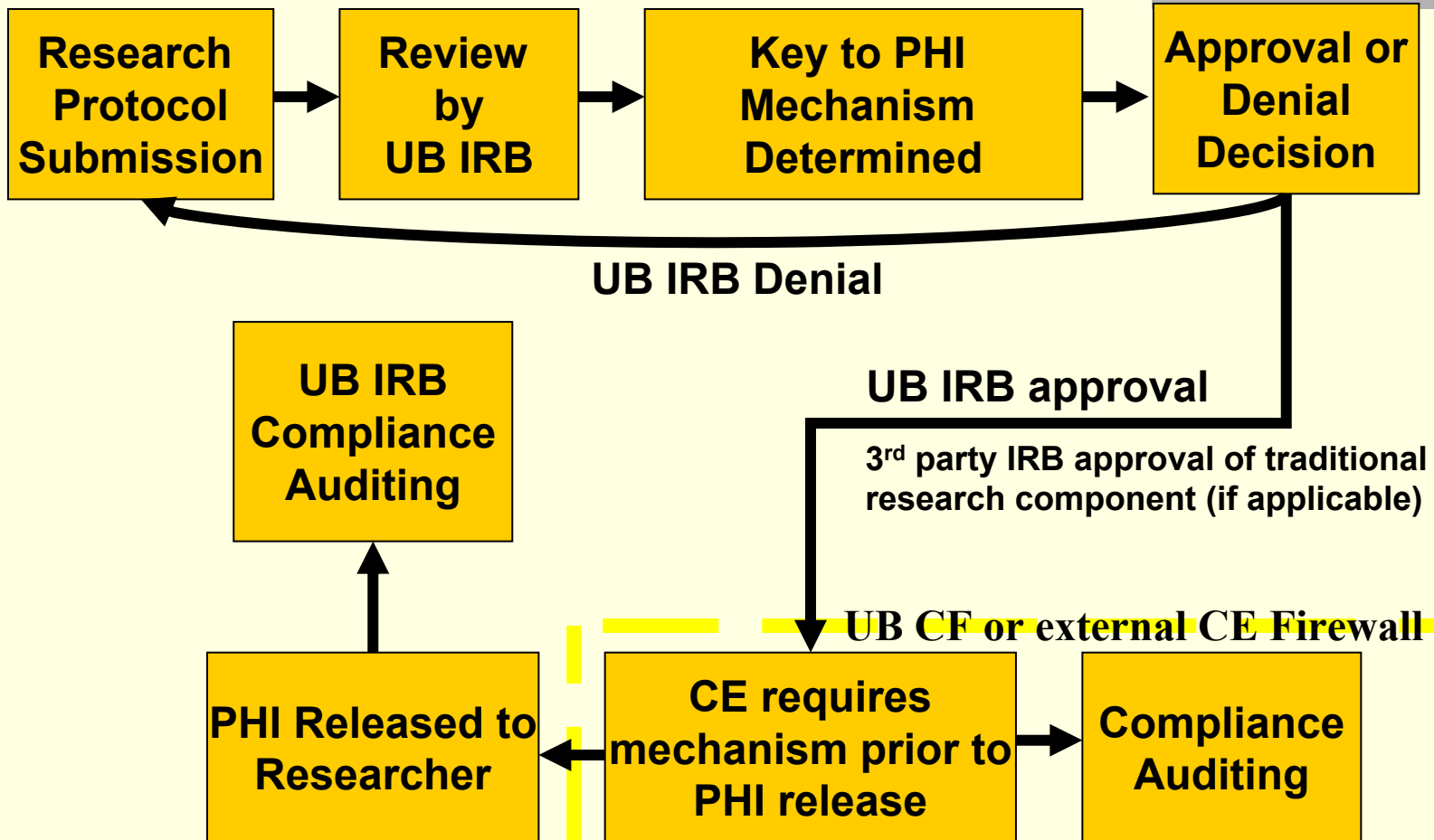
CE Firewall ↑ PHI

***External Covered Entities**

- | | | |
|----------------|--------------------|-------------------|
| RF Health Plan | Teaching Hospitals | UB Practice Plans |
|----------------|--------------------|-------------------|

*Potential for supplying IIHI to UB researchers

UB ACCESS TO PHI FOR RESEARCH (Participating Covered Entities)



Coordination with Covered Entities

- Agree that UB is the entity responsible for HIPAA declarations with respect to its faculty
 - UB faculty do research
 - CE providers deliver health care
- Acceptance of UB IRB review/approval of HIPAA PHI release mechanism for a particular protocol

Coordination with Covered Entities

(continued)

- Collaborative development of common HIPAA forms associated with PHI release to researchers acceptable at all institutions
- Process is ongoing
 - Tweaking process where implemented
 - Reaching out to additional CE to implement
 - Educating community providers participating in research
- Sharing of problems encountered/solutions

HIPAA: Real-Life Research Situations at UB

Identifying Common Research Problems
and
Solving Problems via Thought-Provoking Scenarios

Common Problems

HIPAA Forms

- HIPAA authorization form shootout – whose authorization is “valid”?
 - Philosophy: Since CE is liable under HIPAA, the authorization form that has been reviewed and approved by their legal folks is the one that should be used



Common Problems

Multiple IRBs

- Approach:
 - Make things as uniform as possible for researchers so that HIPAA doesn't become 90% of their workload
 - "Community effort" among Privacy Officers and IRB Administrators to adopt similar or identical forms/procedures
- Protocols involving multiple investigators, multiple institutions, multiple CEs and multiple IRBs – dealt with on a case by case basis with lots of patience

Common Problems

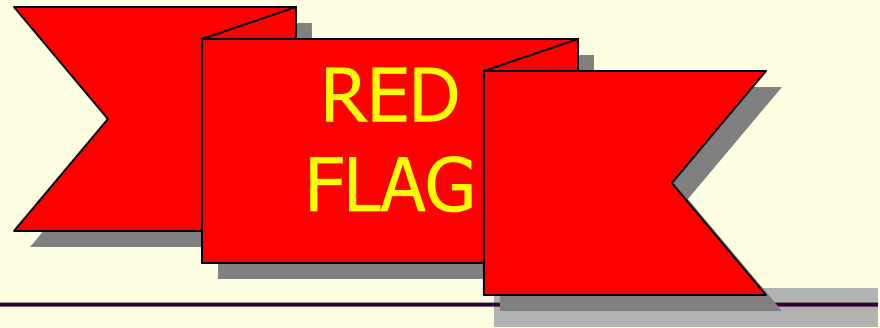
Business Associates

- “Helpful” business associates with their own Business Associate Agreements (BAAs)
 - Many aren’t Business Associates – if they don’t provide a service *to* a CE, they aren’t a Business Associate
 - Solution is usually to ensure that entities such as research sponsors are appropriately incorporated into HIPAA release mechanisms as legitimate recipients of information they require (e.g., for audit functions)



Scenario 1

Business Associates



- Need

Pharmaceutical company wants to sign business associate contract with UB researcher in order to access clinical trial study data associated with drug they provide

Scenario 1

Business Associates (continued)

- Business Associate Agreement (BAA) is not appropriate because
 - UB research function is not a HIPAA covered function
 - Even if UB research function were a covered function, Pharmaceutical company is not providing a service to UB (or CE)
- Solution: Make sure Pharmaceutical company is appropriately listed in the HIPAA authorization signed by study participants

Common Problems

“Research is Exempt from HIPAA”

- HIPAA is not optional and research IS NOT exempt from HIPAA
- Research that is part of the HealthCare Component is fully under HIPAA (privacy, security)
- Even if research is outside of CE, HIPAA still impacts it when PHI comes from CE
 - 7 mechanisms of releasing PHI from CE for research
 - CE accounting for disclosures
 - Business Associate Agreement (BAA) for creating limited or de-identified data sets
 - Data Use Agreement (DUA) for receiving limited data sets

Common Problems

Researcher Confusion



- For UB, simply a matter of education in the 7 HIPAA mechanisms to transfer PHI to a researcher
 - Key is understanding role appropriate activities (health care provider vs. researcher)
- Caution against proceeding on self-derived interpretations of HIPAA
 - Any approach outside of defined institutional policies should be cleared by Institutional Privacy Officer
 - Don't stray too far from source guidance (HHS/OCR)

Scenario 2

PHI for Study Feasibility/Recruitment

UB researcher needs to review PHI held by CE in order to determine

- Is protocol being contemplated is feasible?
- To screen for and recruit protocol candidates

Obtaining authorization not practicable

Scenario 2

PHI for Study Feasibility/Recruitment (continued)

- IF UB Researcher is also a health care provider in CE
 - Reviews Preparatory to Research as a “use” activity of the CE (reviews preparatory ≠ research)
 - Once protocol is approved, can also recruit under “Reviews Preparatory to Research” as a “use”.
- IF UB Researcher is not part of CE
 - Waiver of authorization as a “disclosure” activity

Scenario 2

PHI to Create Limited/De-identified Data Sets

- Need (#2)

Can UB researcher create and keep a de-identified or limited data set using screening information?

Scenario 2

PHI to Create Limited/De-identified Data Sets (continued)

- Creation of de-identified or limited data sets is an activity of a CE
 - IF Researcher is also a health care provider in CE, YES (per CE policies)
 - IF Researcher is not part of CE
 - BAA to create data set
 - OR seek authorization from candidate subject

Scenario 2

PHI to Create Limited/De-identified Data Sets (continued)

- Retaining data for research use is solely an activity of the UB researcher
 - Status in CE does not matter
 - DUA to receive limited data set
 - BAA for non-CE workforce member and DUA may be combined [OCR 12/2002 plain language guidance]
 - OR seek authorization from candidate subject

Scenario 3

Real Life

- Need

Lab supervisor sees copy of IRB letter reminding investigators to be aware of HIPAA PHI access mechanisms

Calls 3rd party CE Privacy Officer with concern about tissue samples being collected/stored for research

Is told tissue samples, both those currently being collected and those in cold storage since 1990, must be destroyed to protect PHI because of HIPAA

Scenario 3

Real Life (continued)

- Solution

Destroy the samples?

NO!

Scenario 3

Real Life (continued)

- HIPAA never requires destruction of data unless contractually agreed to within HIPAA mechanisms
- HIPAA does not apply to any research data in the possession of a UB researcher
- Tissue samples are not PHI
 - No PHI transmitted with the samples; they can be considered deidentified (82533 Federal Register / Vol. 65, No. 250 / Thursday, December 28, 2000 / Rules and Regulations)

Scenario 3

Real Life (continued)

- Assuming PHI involvement, and a CE as recipient, collection and retention are two different issues
- Collection from a CE after 4/14/2003 can continue provided any one of the 7 HIPAA PHI transfer mechanisms to research is in place
- HIPAA addresses retention/use of PHI for research purposes only through implementation details of those 7 transfer mechanisms
 - Emphasis on transition provisions for samples collected prior to 4/14/2003

Scenario 3

Real Life (continued)

- Would destruction of samples ever be reasonable?
 - PHI was transferred with the samples AND
 - Transfer took place after 4/14/2003 AND
 - HIPAA transfer mechanisms were not in place AND
 - The CE providing the samples requested their destruction to mitigate their HIPAA violation AND
 - A judgment call: impact of destruction on the research project (is a subject requesting the destruction?)
 - Implementing HIPAA mechanism, though not retroactive, might be more appropriate for mitigation
 - Obviously: PHI transfer mechanisms should be put in place ASAP assuming CE is still willing to participate in protocol

HIPAA: Compliance Monitoring

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Agenda

Compliance Monitoring

- SUNY System monitoring of campuses
- Campus self monitoring

Compliance Monitoring - SUNY

- Campus Annual Self Assessment
 - Excel tool
 - Supporting documentation (e.g. policies, procedures and forms) should be compiled at the campus and available for submission upon request.
 - Plan of corrective action should be developed for problem areas
- Onsite Audit
 - HIPAA compliance will be incorporated and monitored as part of the established SUNY audit process. Responses to the annual self-assessment will be validated during the onsite visit.

SUNY Self-Assessment Tool

Risk Focused, Excel Based

- Part I – Determination of HIPAA covered functions (10 questions)
- Part II – Program Structure / Administrative Requirements (13 questions)
- Part III – Patient Rights (13 questions)
- Part IV – Business Associate Agreements (7 questions)
- Part V – Workforce Training (6 questions)
- Part VI – Uses / Disclosures (7 questions)
- Part VII – Miscellaneous (protected records, data communication, data mapping; 13 questions)
- Part VIII – Transactions and Code sets (11 questions)
- Part IX – Security (5 questions)
- Part X – Research (12 questions)

SUNY Self-Assessment Tool

Determine Your Status

State University of New York *Sample University* HIPAA Compliance Self-Assessment

Based on your responses:

You are a HIPAA Covered Provider

You Are Not a Clearinghouse

You Are Not a Health Plan Covered by HIPAA

Your Campus has Research that needs to comply with HIPAA

SUNY Self-Assessment Tool

Research Section

1. Has covered research been included in the campus' compliance activities?
2. Is a dynamic list of studies meeting the criteria established for inclusion as part of the covered entity maintained at the campus? (NOTE: Only a listing of studies needing to comply with HIPAA need be maintained for purposes of HIPAA)

SUNY Self-Assessment Tool

Research Section
(continued)

3. Does your campus have guidelines in place related to Reviews Preparatory to Research?
4. Does your campus have guidelines in place related to Waiver of Authorization?
5. Does your campus have guidelines in place related to Limited Data Sets with a Data Use Agreement?
6. Does your campus have guidelines in place related to Research on Decedents?

SUNY Self-Assessment Tool

Research Section
(continued)

7. Does your campus use the RF approved Standard Agreement Language as minimum necessary for appropriate contractual documents?
8. Does your campus have guidelines in place related to Uses and Disclosures With Individual Authorization?
9. Does your campus have a mechanism to track research disclosures?

SUNY Self-Assessment Tool

Research Section
(continued)

10. Does your campus have guidelines in place related to De-identification of Data?
11. Have you defined your research record set? (Separate from the campus designated record set)?
12. Do you have a process in place for accounting of disclosures from research records when a waiver of authorization has been granted?

SUNY Self-Assessment Tool

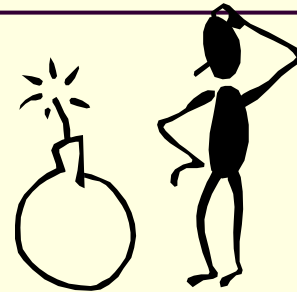
Special Demonstration

This is where we connect to a visual of the
SUNY Self-Assessment Tool

a special demonstration
for the NCURA audience

Lessons Learned

- Confusion can be opportunity



- Team selection and buy-in by leadership is critical



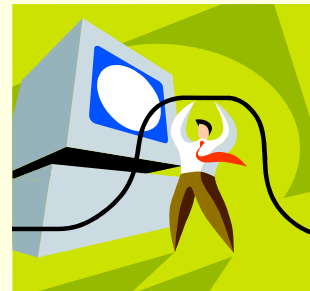
- Set realistic goals and timeframes



Lessons Learned

(continued)

- While beauty is in the eye of the beholder, covered functions and activities can be defined by operations



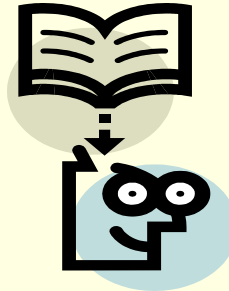
- Document, document, document



Lessons Learned

(continued)

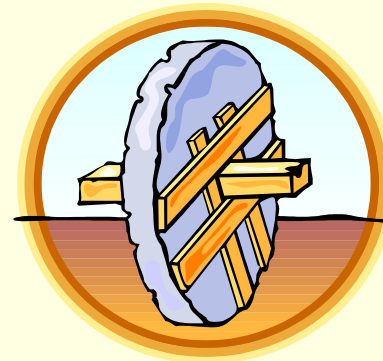
- Educate, re-educate



- Take advantage of existing resources



- Adapt do not re-invent the wheel



HIPAA Helpful Resources

- Department of Health & Human Services (DHHS)
FAQ <http://privacyruleandresearch.nih.gov/faq.asp>
- DHHS Office for Civil Rights
FAQ http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php
Medical Privacy National Standards <http://www.hhs.gov/ocr/hipaa>
- DHHS Office of Assistant Secretary
Administrative Simplification <http://aspe.hhs.gov/admsimp/>
- SUNY University at Buffalo
Guidance & Forms <http://www.hpitp.buffalo.edu/hipaa>
See "Researchers" Link for information specific to researchers

HIPAA Helpful Resources

(continued)

- American Hospital Association: Hospital Connect
<http://hospitalconnect.com>
- American Health Information Management Association
<http://library.ahima.org>
- HCPro's Healthcare Marketplace
<http://hcmarketplace.com>

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Questions?

