

**HIPAA:
A YEAR LATER,
APPLICATION STRATEGIES
FOR SUCCESSFUL CLINICAL
TRIALS**

3 Objectives of Session 5.07

The participants will:

1. **Apply the HIPAA Privacy & Security terminology to running a clinical trial:**
 - Identify when authorization or waiver of authorization is acceptable,
 - Define recruitment activities where authorization or waiver of authorization is not required.

Objectives of Session 5.07 (cont.)

The participants will:

2. Apply the HIPAA Privacy & Security Regulations to the responsibilities of the study team:

- Research Site, Sponsor, IRB, Vendors

Final Objective of Session 5.07

The participants will:

3. Identify successful study management strategies post HIPAA.

***Refer to Handout:
HIPAA TERMINOLOGY RELATED TO CLINICAL RESEARCH**

Security & Privacy Rule Distinctions:

- They are inextricably linked.
 - The protection of the privacy of information depends on the security measures to protect the information.
- Difference = is the scope of the Security Rule only applies to information in electronic form. The Privacy Rule looks at information in any form.
- 21 CFR part 11 preparedness for sponsors, sites & vendors.

Security Rule:

- Designed to be Scalable & Flexible enough to meet different CE circumstances
- Standards:
 - Written to be as generic as possible to allow for various approaches or technologies.
 - Internal & External networks to be dealt with the same
 - Security Incident
- Implementation Specifications:
 - Provide Instruction on implementation of security standards
 - Required or Addressable (flexible)
 - Risk analysis to determine need for addressable specifications
 - Smaller CEs compared to larger CEs

First You Must Have a Clear Answer to the
Question (s):

■ **Am I a Covered Entity (CE)**

and/or

■ **Am I working with or for a Covered
Entity (CE)?**

Covered Entity (CE)

- A person, group or organization that must comply with HIPAA
- Covered functions:
 - Treatment, Payment & Operations (TPO).

NOT Research itself. But if the research involves treatment by a CE or storage of records with identifiable PHI by the CE then the Use & Disclosure of that PHI is covered under HIPAA.

Covered Entities

■ Qualifications of a CE:

- Transmit health information in electronic transactions. Electronically transmit at least one of the following:
 - Health care claims or equivalent encounter information
 - Health care payment & remittance advice
 - Coordination of Benefits
 - Health care claim status
 - Referral certificate & Authorization
 - First Report of Injury
 - Health claims attachments

Covered Entities

■ Types:

- Health care providers
 - Research
- Health Plans
- Health care clearinghouses
- Hybrid Entities
 - A company or person with one or more components that fit into one of the categories of a covered entity.
They will have some functions covered and some not.

Consider When Answering the Question (s):

- **Do I have Clear definitions**
 - **Of your Entity**
 - **Independent Research Site**
 - **Blood & Tissue Repositories**
 - **Hybrid Entities**
 - **Of your Associates**
 - **Research Sponsors**
 - **Consultants**
 - **Vendors**
 - **Sales Reps**

Covered Entity Decision Tool:

Refer to table 1-2

Am I A Covered Health Care Provider?:

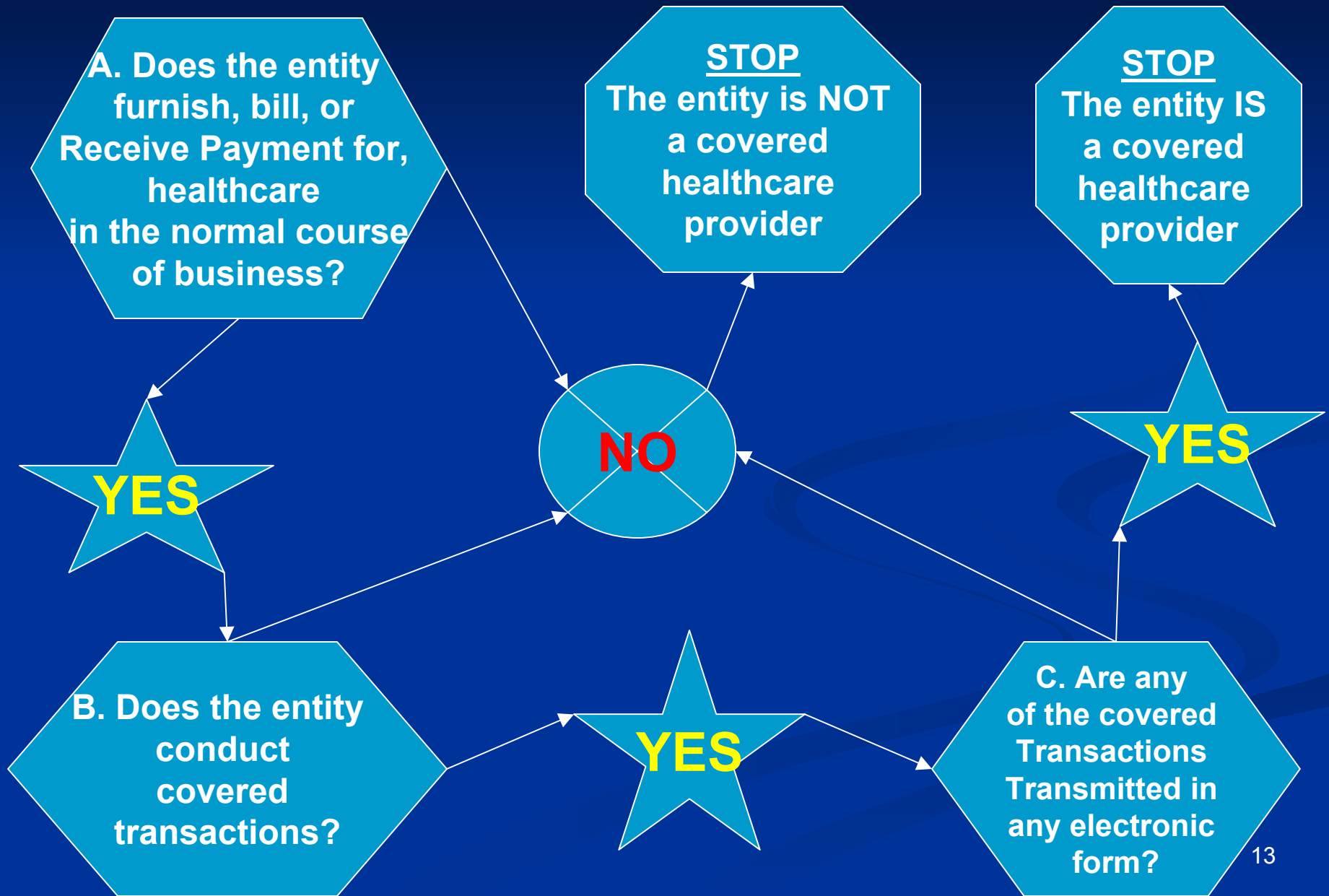


TABLE 1-3A: Scenario

- An incorporated internal medicine practice has a second business, a clinical research site. The practice has two satellite offices where patients are seen for both office and study visits. Patients are referred to the research site from the medical practice & from outside advertising.
- What is the covered entity(s) in this situation?

TABLE 1-3B: Scenario

- An independent research facility contracts physicians to serve as investigators to various sponsors' clinical trial protocols.
- What is the covered entity(s) in this situation?

TABLE 1-3C: Scenario

- A pharmacy within an academic medical center serves most clinical departments within the institution, including the outpatient clinics and clinical research department.
- What is the covered entity(s) in this situation?

TABLE 1-3D: Scenario

- A central lab is contracted to be a vendor for a drug sponsor's clinical trial. The central lab also serves as a local lab for many physicians' offices.
- What is the covered entity(s) in this situation?

HOW PHI CAN BE USED FOR CLINICAL RESEARCH

- CEs PERMITTED TO USE OR DISCLOSE PHI FOR RESEARCH: 45 CFR 164.512
 - With Individual Authorization, or
 - Of Decedents' information: Not covered by The Privacy Rule (refer to handout), or
 - Without Individual Authorization Under Limited Circumstances:
 - With an approved Waiver of Authorization, Review Preparatory to Research, or Under a Limited Data Set Agreement.
 - Minimum Necessary Standard

INDIVIDUAL AUTHORIZATION TO USE OR DISCLOSURE PHI:

- 9 mandatory elements: See table 1-4
- May be a separate document or combined with the ICF.
- Must be specific to the disclosure. Not a blanket authorization.
- Must announce & offer review of the CE Notice of Privacy Practices document.
- No Mandatory review required by IRB or Privacy Board under HIPAA.

TABLE 1-5A Scenario
INDIVIDUAL AUTHORIZATION TO USE
OR DISCLOSURE PHI:

- During a pre-study visit, a sponsor discusses the informed consent process and states that the authorization for disclosure of PHI is included in the ICF.
 - As a research site, what should be considered?

Authorizations

- Combined or Not to combine?
 - When combined does not work
 - Who Decides?
 - Flexibility
 - Who determines language?
 - Does it contain the required components?
 - Does the subject understand?
 - Where to find examples of combined examples?
 - NETWORK
 - WEBSITES

WAIVER OF AUTHORIZATION:

- Requested for access to PHI from an IRB or Privacy Board.
- Must prove no more than minimal risk of the disclosure without authorization or obtaining authorization would be impracticable.
- Partial waivers may be practical where authorization for use or disclosure of all PHI is thought to be not necessary deemed by the privacy board or IRB.
- Alterations in authorizations may be approved or requested by the privacy board or IRB for removal of certain PHI from disclosed or used information.

Required Documentation of the Waiver or Alteration:

- Must include a statement identifying the IRB or Privacy Board that made the approval.
- The date of the approval.
- Statement that no more than minimal risk to the privacy of the individual was evaluated and the required elements are in place. (refer to handout)
- Statement that the research could not be practically conducted without the waiver or alteration and without access to and use of the PHI.

TABLE 1-5B Scenario

WAIVER OF AUTHORIZATION:

- During a clinical trial, a procedure is added to the protocol where the sponsor hires an additional outside vendor to analyze the results.
 - Discuss this event and what the CE would have to consider relating to the HIPAA Regulations.

REVIEW PREPARATORY TO RESEARCH:

- Considered part of Operations (TPO)
- No Authorization needed if No PHI leaves the CE.
 - If the review is done by an outside source, no PHI in any form can be removed from the CE. (i.e. Sponsor)
 - Reviewer can take notes, but no PHI in any form can be removed or used by the researcher if not an employee of the CE. (may give notes to site staff)
- The CE may hire a BA to do the review.
- CE needs Assurance from outside researcher that the PHI will not be removed or used. (SOP & QA)

TABLE 1-5C Scenario
REVIEW PREPARATORY TO
RESEARCH:

- A research site for a sponsor protocol has been asked by the sponsor to provide them the number of patients they have seen in the last 6 months with elevated RBCs that weigh over 200 pounds.
 - Considering HIPAA Regulations what are the sites options, list at least 4 options.

LIMITED DATA SET & DATA USE AGREEMENT:

- Signed agreement with recipient of PHI for limited use and safeguards.
 - How will it be used and how will it be protected.
 - Agreements cannot include allowances for future uses or disclosures of the data set.
- Only used for the purposes of Research, Public Health or Health Care Operations.
- No authorization necessary. But agreement needed even with direct employees of CE.*
- PHI with Limited identifiers allowed: Year, zip code, city, See Table 1-5A for restrictions.
- Requires tracking of disclosures.

LIMITED DATA SET & DATA USE AGREEMENT:

- May be good to use if pre-screening information needed by researchers prior to authorization = proof of fair sampling and verifying site pre-screening efforts for sponsor.
- A CE may hire a BA to create the Limited Data Set.
- Specific Provisions in the agreement: See Table 1-6B

TABLE 1-5D Scenario
LIMITED DATA SET & DATA
USE AGREEMENT:

- You are on a committee to write the new SOP for HIPAA regulations in regard to Limited Data Set & Data Use Agreements.
 - What would your SOP include?

INVESTIGATION & ENFORCEMENT:

- Department of Health & Human Services Office of Civil Rights (DHHS OCR)
- Civil Penalties have been established for non-compliance
- 4/15/03 HIPPA Privacy Procedural Enforcement Rule
- Penalties may be waived or reduced if the compliance failure is due to reasonable cause and not willful neglect and correction within 30 days.
- CEs need to show good faith efforts.

RESPONSIBILITIES OF THE STUDY TEAM

- Clinical Research Sites & IRBs
- Sponsors of Research &
Associates

PART I: The Clinical Research Sites

- **Assess current compliance of existing SOPs**
- **Plan a compliance strategy**
- **Identify resources to help with compliance**
- **Develop training for site staff**
- **Implement required activities for compliance**
- **Apply GCP and GPP to study management**
- **List methods to stay current with regulations**
- **Audit site privacy and security practices**

PART II: Sponsors of Research & Associates

- Assess compliance of current or potential sites
- Identify when provisions of assurance of protection of privacy of PHI is needed.
- Recognize study practices that may create conflict in site compliance
- Defend the need for previously collected data after subject revocation of authorization

Development & Approval of Policies & Procedures to Support HIPAA:

- Guidelines:
 - Policy Creation and Maintenance Mandatory: (164.530j)
 - Infers knowledge of good policy & procedure development
 - Must store 6 years from creation or last in effect
 - All documents, templates, authorizations, agreements
 - Annual Compliance Report (160.310)
 - Content not specified/ Send When requested by DHHS
 - Disclosure Tracking
 - IRB relationships

Minimal Requirement of Policy:

- Approved by Senior Management
 - Appoint Security and/or Privacy Official

- Required Training
 - How Much?
 - How Often?
 - Certification?

- Covers All Requirements of Law
 - Can be more impacting
 - Cannot contradict

Examples

- Employees will attend the companies yearly 1st quarter Privacy and Security Rule Training within their assigned department.
- Workers will satisfactorily pass the company's HIPAA Privacy & Security Rule Exam 30 from first day of employment and thereafter within 30 days of their annual performance review

Procedure Development:

- Tailored to CE
- Procedures Cannot
 - Excuse actions required by law or
 - Permit actions against the law
- May be changed with modification to Privacy Practices
 - Be sure that your Privacy Practices can be changed
 - & this fact is noted.
- Separate or within SOPs?

Technical and Operational Considerations:

- Officer Appointment
 - Job Descriptions

- Task Force Members
 - Finance, Regulatory, Clinical, Management, Marketing, Technical Writers, Consultants, and . . .

Documentation Compliance:

- **Assess what you currently have and identify additions and edits:**
 - Approaches:
 - Document Inventory
 - Current SOPs as Tool

Examples

- Document Inventory
 - TABLE 2-1

- SOP Table of Contents
 - Which Sections Affected by HIPAA
 - Terminology
 - Review Procedures
 - Determine revision vs. creation
 - TABLE 2-2

Part I Clinical Research Sites

PLAN:

- Task Force
- Purchase or Create (Combo)
- Detailed Timeline
- Meeting Minutes

Part I Clinical Research Sites

IMPLEMENT:

- Privacy/Security Official Appointment

- Writing the policy
 - Examples: Waiver of Authorization Application, Tracking & Reporting Privacy Violations
 - Review the Regulations
 - Goal Identification
 - Write & Test Draft
 - Develop Procedures from policies

Development of Procedures:

- Foundation of Training

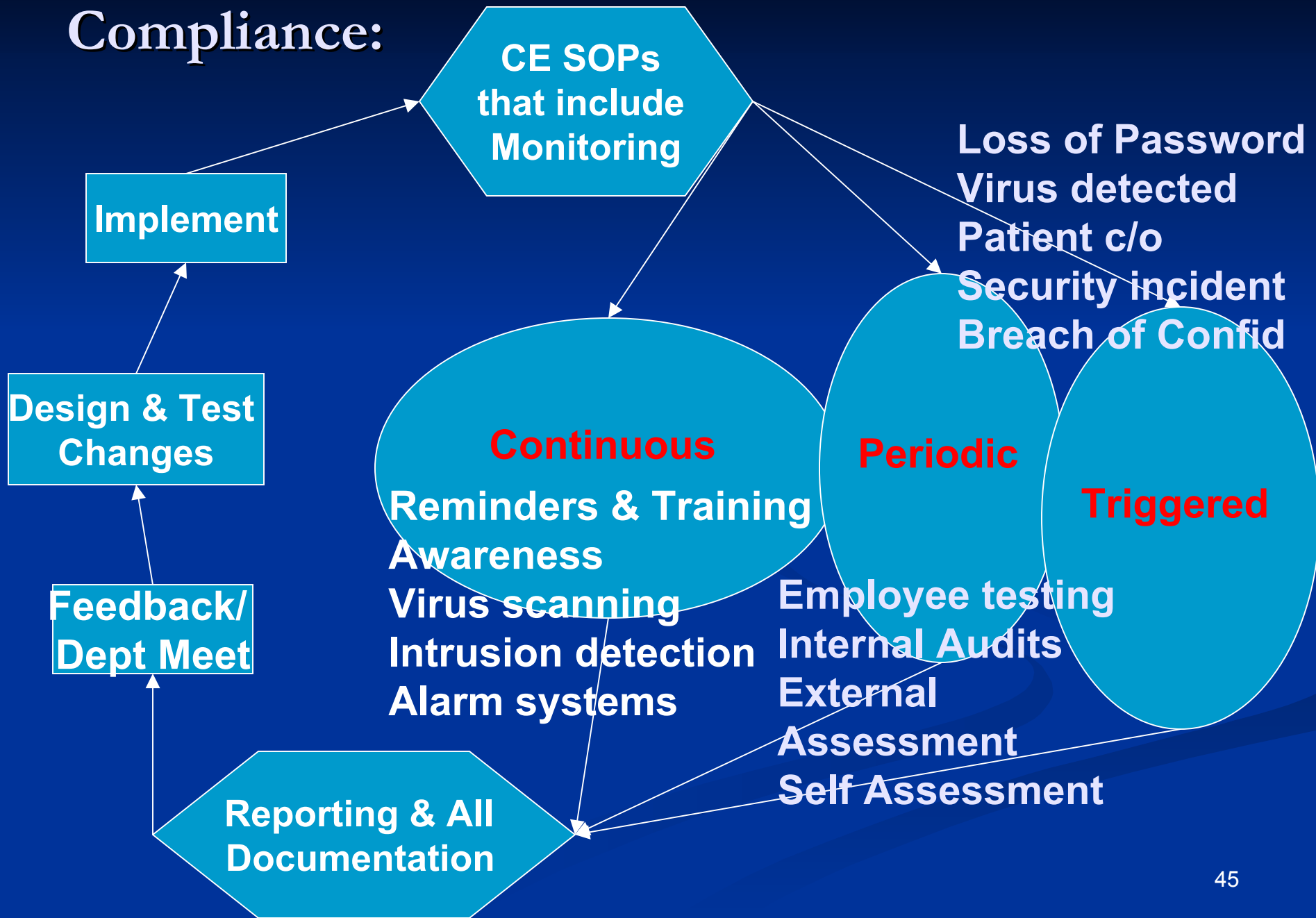
Senior Management Wants to Know:

- Probability of Risk Threat occurring
- Impact of the Threat
- Resources to Reduce the Risk

Monitor: Circular Process

- According to timelines
 - Make Modifications
 - Track Changes
 - Implement
- Repeat process

The Circle of Implementation & Monitoring Compliance:



Part I Clinical Research Sites

Resources:

- Template Creation
- Guidance Documents
- Network

Staff Training:

- Classroom
- Application: On the Job & Test
- Documentation: Training Files
- Dynamic Process

Good Clinical Practice & Good Privacy Practice

GCP & GPP

➤ **HIPAA Regulations do Not override The
Common Rule or FDA's Human Subject's
Regulations**

■ **Scenario**

TABLE 2-3A Scenario

You are contacted by a Sponsor requesting copies of source documents supporting CRF entries for all subjects enrolled in Protocol XXX123 for unapproved product ABC123. This protocol has been closed for 3 years at the site. The correspondence states that this was requested by the FDA in response to their NDA for product ABC123.

- **Research Site:** What would be your response to this request? What policies at your company apply to this situation? What HIPAA Privacy Regulations are applicable here? What FDA Regulations are applicable here? Does this contradict any HIPAA Privacy Regulations?
- **Sponsor:** How would you respond to the FDA request considering FDA & HIPAA Regulations?

GCP & GPP

➤ **HIPAA Regulations Preempts State Laws that are contrary to the Privacy Rule or offer individuals lesser protection for medical privacy or fewer right to access to health information.**

■ **Scenario**

TABLE 2-3B Scenario

- You are a CE that is conducting medical device studies. During the procedure for insertion of the device the medical liaison must be present to shadow during the procedure.
 - What regulations should be considered when screening the subjects?

TABLE 2-3C Scenario

- You are a CE that is using a central IRB arranged by the sponsor. What study documents does the IRB have to review prior to subject enrollment?
 - Reference Regulation sources FDA & HIPAA.

■ **Assess Site and Vendor Compliance**

- Risk of Knowingly using Non-Compliant Sites
- Proof of Compliance/ Good Faith Effort
 - SOPs, References

■ **Assurance of PHI Protection from Recipients**

- Sponsors of Research to Site-Contract
- BA Agreements
- Review Prep to Research
- Data Use Agreements
- Authorizations
- Waivers of Authorizations

Practices that Cause Conflict in Compliance

- Pre-screening Logs
- Sponsor SOPs that require sites to ? if GPP
- Why asking for the information

Protection of the Integrity of Study Data

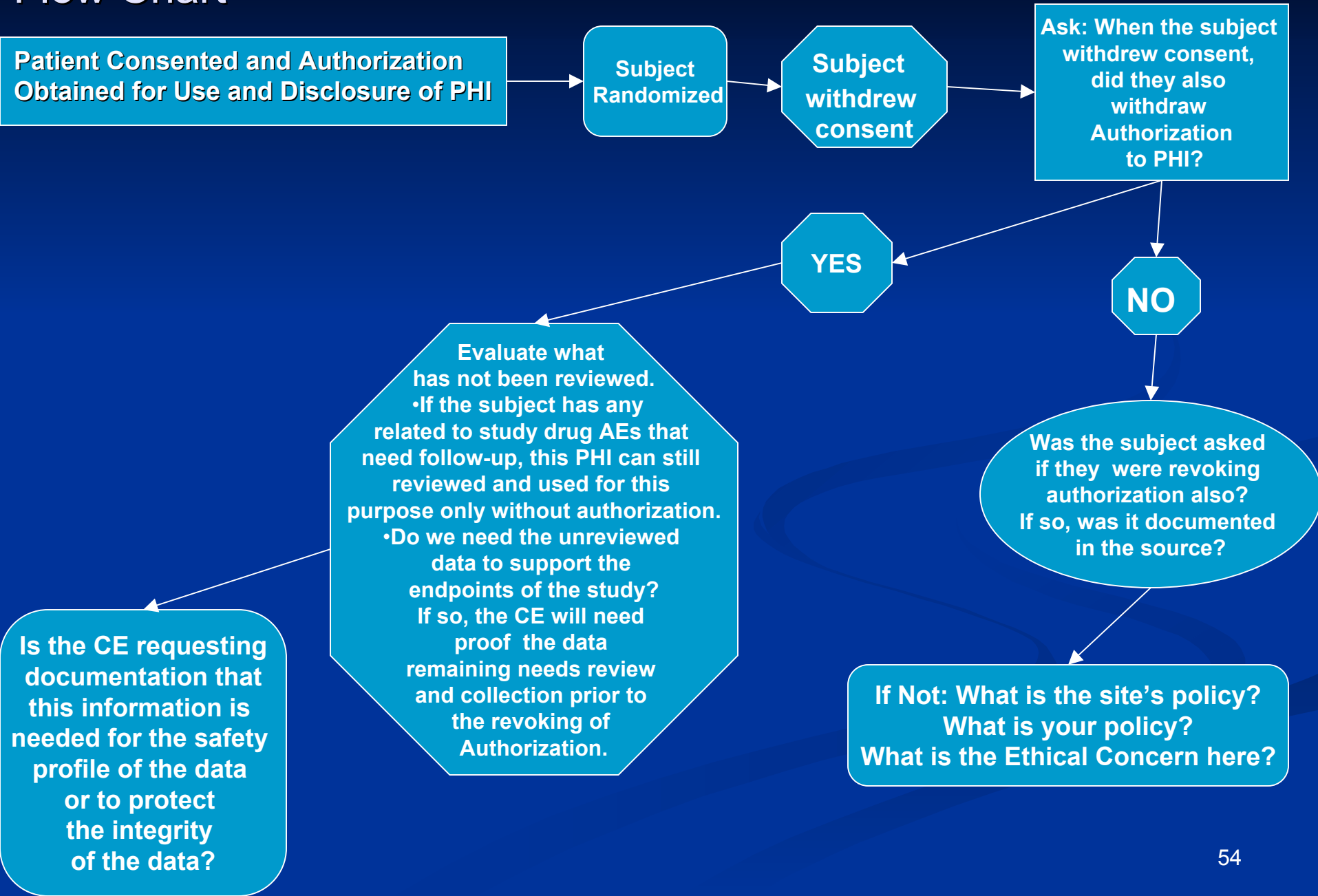
➤ Revoking

- Authorization
 - Must be in writing
 - Need policy
 - Sponsor to provide proof need data to protect integrity of the study

VS.

- Withdrawal of Informed Consent

Withdrawal of Consent/ Revoking of Authorization: Flow Chart



Development & Approval of Policies and Procedures

- Same as Clinical Research Sites

TABLE 2-5 Scenario:

You are a Sponsor conducting a multi-center trial. One of the site milestone payments is based on pre-screening activity. You require the sites to send a weekly pre-screening log in by fax.

What would the CE be able to supply on a log and why?

Strategies for Successful Site Management

Post HIPAA

SITE & SPONSOR REACTION AND INTERACTION

- “My Monitor does not understand HIPAA”
- “I need help with the development of the Authorization”
- “Our IRB must review all our Authorizations; the approval will be delayed.”
- “I need more money in my study budget.”
- “I am confused. I see different levels of compliance on by sites and by sponsors due to varied interpretation.”

SITE & SPONSOR REACTION AND INTERACTION

- “The sponsor will supply the authorization for my studies for us to participate.
- “This is the straw that broke the camel’s back. We will not do research. It is too risky & regulated.”
- “You do not have access to all the subjects medical record, due to minimal necessary.”
- “ALL who enter here are BAs.”
- “Our Authorization must be separate from the ICF.”

SITE & SPONSOR REACTION AND INTERACTION

- Do We Need to Re-evaluate?
- Site/ Sponsor Training Vary
 - Coffee break
 - Huge t-con where no one could hear
 - General Intro for company re:to Personnel Department

HIPAA & Affect on Work Responsibilities:

- *Project Managers*
 - Policy Development
 - Study Vendor Selection
 - CRO
 - Central IRB
 - Central Lab
 - More
 - Contract Negotiations
 - Sites, vendors, contractors
 - Study Budgets
 - IRB costs, Overhead
 - Protocol Timelines
 - Site Selection
 - Study Documentation
 - Training

HIPAA & Work Responsibilities (cont.):

- *CRA Managers*
 - Training
 - Hiring, permanent & Contract
 - Policy Development

- *CRA's*
 - Site Selection
 - Site Visit Prep
 - Documentation Where & What
 - Transporting Patient Data
 - Training

HIPAA & Work Responsibilities (cont.):

■ *CRCs/Investigators*

- Policy Development
- Visit Prep
- QA
- Privacy Officer Appointment
- Sponsor/ Study Selection
- Budget Negotiations
- Working as a CE
- BA agreements
- Tracking Disclosures
- IRB/ Privacy Board Selection
- Training

■ *IRBs*

- Privacy Board Role?
- Policy Development
- Training
- Review of Waivers, Data Use Agreements

HIPAA & Work Responsibilities (cont.):

- Site, Sponsors, Vendors will need to evaluate each other's preparedness and policy development.
- Scenarios

TABLE 3-1A Scenario

- During a phase III study the sponsor adds a new lab test. This requires blood that has already been drawn be sent to another lab not currently on the 1572 for analysis.
 - List what should be considered in this situation prior to implementation?

TABLE 3-1B Scenario

- The sponsor is in the selection process for a central IRB for a new study.
 - What additional information would the Sponsor need to assess prior to making the decision?
 - What information would the site need to find out about the central IRB prior to accepting the study or use of the central IRB?

TABLE 3-1C Scenario

- During a study a subject calls the investigator and states they want to withdraw from the study.
 - List what actions should be taken at this point?

TABLE 3-1D Scenario

- During site selection, a CE requested the sponsor explain how they would assure the protection of the subject's PHI during and after the study.
 - What would be an acceptable answer and why?

Strategies for Training the Project Team:

- The content is not exciting and may even produce frustration, boredom?? You know your audience. Make it something to remember.
- Preliminary Questions to Answer
 - Are we responsible for this?
 - Is it necessary?
 - If so, to what level?
 - How detailed?
 - How to track it?
 - How to test it?

Strategies for Training the Project Team:

- Balancing Time, Cost and Effectiveness
 - Incorporate into corporate orientation (do we have time for one more thing?)
 - Lunch & Learn Sessions: (Participation?)
 - Each clinical department to come up with plan for training: (How do we assure consistency in content)
 - Send out a scout & bring back to department to present
 - Regulatory department's role
 - SOP revision? Yields training/ EVR or IVR
 - Train Contractors? Require Contractors proof of training.

- SOP Revision
 - Will this be revision or creation?
 - Follow your Procedure for Revision of SOPs

Site Visit Report Revisions:

■ Evaluation Pre-Study Visits

- Addition of Site HIPAA Compliance Questions

- Include Action Plans for Compliance and Timelines for Assurance Requirements

- Questions:

- Privacy Practices
- Pre-screening Practices
- Authorization
- Training Documentation
- Minimal Necessary
- Vendors
- Assurance

■ Example Questions:

1. Does your facility have a policy relating to the process of obtaining AUTHORIZATION FOR TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION? Yes or No

If yes, describe: _____

2. Do you have a Privacy Officer? Yes, No

If yes list:

Name: _____

Telephone #: _____

3. Do you have A Notice of Privacy Practices? Yes or No/ Copy obtained?

Initiation Visits and/or Investigator Meeting:

- Addition of Site HIPAA Compliance Questions:
 - SOPs, Timelines, Documents, Activation date
- Include Action Plans for Compliance: Risk of Unresolved Action Items
- Document Statement of Assurance of Protection of PHI for all patients.
 - Sites' requirements for assurance?
 - Early Identification and follow-up

Interim Monitoring Visits:

- List How, When, and by Whom Authorization was obtained
- Monitor for an Revoking of Authorization and Changes in Privacy Practices
- Monitor for Privacy Officer Appointment & Changes
- Careful to Resolve/ Add Action Items for GPP and Follow through

Close-out Visit:

➤ Reassurance

➤ Action Item Resolution

Follow-Up Letter:

- Include Assurance/ End date on Authorization
- Document Authorizations/ with ICFs
- Document GPP
- How often?

Sponsors: Help sites obtain the information they need up front on the disclosed PHI.

Sites: Let Sponsors know up front what assurances are needed & policies you have in place.

Summary:

Let's work better together
to uphold the Privacy &
Security of Subject Data; then
ultimately we will increase the
confidence of the general public
in Clinical Trials.

Question & Answer Session

Extra Questions

- Which of the following is a Covered Entity under HIPAA?
 - A Central Laboratory as a vendor of the sponsor of a clinical trial.
 - A Pharmaceutical Companies Phase I Oncology Unit.
 - A Contract Research Organization Clinical Data Management Department.
 - The Health Plan Administrator of a Pharmaceutical Company
 - a & c only
 - a & d only
 - b & c only
 - b & d only

- Which of the following is always Protected Health Information under HIPAA?
 - Information used by a sponsor collected at site.
 - Information regarding a decedent's family member.
 - Electronic medical records maintained at an Academic Medical center.
 - Data collected in CRFs.
 - a & c only
 - a & d only
 - b & c only
 - b & d only

- The project team can document assurance for the CE of maintaining the subject's privacy rights by which of the following:
 - Adding a summary statement in visit follow-up letters
 - Adding a question addressing this issue to the monitoring report template
 - Provide a written statement of how & for what time period the PHI will be protected
 - Include a statement in the ICF that documents the assurance of the protection of the PHI
 - a, b & c
 - b, c & d
 - a, c & d

- An independent consultant is hired by a free-standing research facility not affiliated with a medical facility to enter data into electronic CRFs for three different studies. Under HIPAA, this research facility:
 - would initiate a Business Associate Agreement with the consultant.
 - must initiate a confidentiality disclosure agreement with the consultant.
 - is not governed directly under HIPAA.
 - Is a hybrid entity and must initiate a Data Use Agreement

- A CE office has restricted access controlled by a receptionist, open storage of PHI is acceptable if:
 - The office is locked and alarmed after work hours
 - There is a security guard in the facility
 - Everyone, including the receptionist, are required access to all patient records in order to do their jobs
 - It is deemed secure by the HIPAA compliance officer

- When conducting a clinical trial, as a CE what regulations should be followed?
 - ICH Guidelines
 - FDA Regulations or Common Rule
 - Applicable State Law
 - Privacy & Security Rule Regulations
 - a, b & c
 - a, c & d
 - b, c & d
 - All of the above