Privacy and Confidentiality.

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Privacy and Confidentiality

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Objectives

- Identify System Mechanisms that Maintain Participant Privacy and Confidentiality
- Discuss Strategies that Ensure Protections to Research Participant Privacy and Confidentiality

Outline

- Review a High Profile Case of Multiple Errors Effecting Individuals in the Name of Medical Innovation
- Provide background information explaining the current definitions and regulations related to Privacy, Confidentiality and Research
- Present Hypothetical Scenarios with Best Practice Solutions

HeLa Cells

- Followed standard acceptable practice at the time
- Can’t always anticipate phycological harms related to research even if you follow accepted guidelines and regulations at the time
- There are ethical principles in addition to regulations that need to be applied to all research

Ethical Principles

- Respect for Persons
- Beneficence
- Justice

- Privacy and confidentiality fall under Respect and Beneficence

Privacy & Confidentiality

Basic Concepts Applicable to the Protection of Human Subjects Engaged in Research

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Hypothetical Situations

- Not related to any incidence or situations that have occurred within Lehigh Valley Health Network
- Any association with any employee is purely coincidental
- All of the following scenarios are pure FICTION for educational purposes only

Invasion of Privacy

- RN on 7th Floor A wing going to school for her master's degree and is required by her program to conduct a research study
- Qualitative Nursing Study on Coping Mechanisms Utilized by Individuals and Their Families when Diagnosed with Terminal Illness

Set the Stage

- RN Betty is assigned to rooms 1-6 and her co-worker is caring for patients in rooms 7-12. She overhears during report that a 42 year old women in room 12 has been diagnosed with stage IV melanoma
- Betty stops in room 12 at lunch to ask the women is she would consent

Background

- Study is IRB approved
- Requires participants sign informed consent
- Potential participant meets criteria for enrollment
- Patient in room 12 is listed as a “Do Not Announce”
- She is also an attorney that sits on the IRB at Thomas Jefferson

Situation

- Patient declines study participation and is very upset
- Contacts 402-Care to log a formal complaint
- Contacts OHRP to report an invasion of her privacy

Panel Discussion

- Legal issue
- Risk management issue
- Research Protection issue
- Ethical Issue
- Employment issue

Best Practice

- Implement plans to AVOID the situation
- Principal Investigator versus Health Care Professional involved in Care Delivery
- Simple solution is to utilize the care delivery team for permission or an introduction

Failure to Protect Sensitive Information

- Research involving Existing Data obtained through Medical Record Review Only
- The Hypothesis is that Individuals from Mid to High Socioeconomic Brackets are More Compliant with HIV treatment versus Individuals from a Low Socioeconomic Bracket

Background

- IRB Approved
- HIPAA waiver of individual patient authorization has been granted
- Researchers will de-identify the data set at the earliest time possible
- All patients treated at the Temple HIV center over the past five years will have their records reviewed for this study

Set the Stage

- Mary is a Temple Employee that has been HIV+ since a needle stick at work
- She has been a patient at the clinic for the past 5 years since Temple is “self” insured
- She has not disclosed her HIV status to anyone other than her husband and goes to her appointments up the back stairs
- Her mother has called her frantic since she just heard her daughter is HIV+

Situation

- Cleaning lady for the research office noticed a data collection form with Mary's name left on the research associate's desk
- Cleaning lady is a friend of Mary's mom who sincerely inquired about her daughter's health
- Mary has contacted the clinic's risk management department to log a complaint and request a full audit disclosure of everyone that has viewed her medical records

Panel Discussion

- Legal issue
- Risk management issue
- Research Protection issue
- Ethical Issue
- Employment issue

Other Situations that may Arise From Inappropriate Disclosure of Sensitive Information

- Loss of Employment
- Loss of Health Coverage
- Inability to Obtain Insurance
- Social Stigmatization
- Embarrassment
- Loss of Personal Respect

Best Practice

- Different than clinical care – Do NOT use names
- PHI should be the minimum necessary to conduct the research
- Codes with temporary key links
- PHI on and in computer systems have security
- Once the data is extracted from those systems researchers must implement their own security
- Certificates of Confidentiality

HIPAA Waiver versus Authorization

- HIPAA is granted by the IRB or privacy board
- Must meet certain criteria to be waived
- With a waiver the data set needs to have PHI removed at some point
- Written authorization - HIPAA section of the informed consent document
- Authorization has certain elements that need to be disclosed to the participant

Information Extracted from Medical Records

- Not always just research
- May have some of the same risks associated with inappropriate disclosure
- May not be “sensitive” information
- What one person views as acceptable may not be acceptable for someone else

Privacy is Subjective

Simple Tips

- What do you need to identify the records that will be reviewed?
- What information are you after?
- Inappropriate or incidental disclosure is easily accomplished with a name
- An account number or medical record number allows access to the record
- Sometimes aggregate info is all that's needed and out of habit names are collected

Simple Tips

- Identify data points that needed early on when designing the study
- Plan for the timing and the individual responsible for de-identifying the data set
- Eliminate PHI whenever possible
- Examples include dates of admission and discharge – Instead collect LOS
- Two forms of identification is recommended so use initials and MR#'s so to de-identify you will only need to delete the MR field

Storage of Records and Data

- Where will the records be stored (both the data set and the source documents)?
- Who has access to the records/data?
- Who is responsible for the records?
- If applicable, who will de-identify the records
- Where will the records be retained?

Additional Topics for Discussion

- QI/QA
- Evidence-Based Practice
- Presenting or publishing QI/ QA or Evidence-Based Practice Integration Experiences
- Tissue Banking
- Genetic Research

Waiver of Documentation of Informed Consent

- One mechanism to protect participants privacy and confidentiality
- Minimal Risk studies
- The only “Link”
- Information is still provided to the participant they just do not sign an informed consent document

Research Involving Genetic Information

- Regulations currently protect participants involved in genetic research
- GINA
- Informed Consent
- De-identifying samples
- Disclosing that there is no monetary or proprietary compensation

Is that enough?

- DNA can be used as legal evidence to identify someone
- As technology improves will the regulations be out dated and offer little protections
- Insurability is of major concern
- National Electronic Medical Record will challenge or compromise privacy and confidentiality

Closing

- Researchers have a legal and moral impetus to ensure research is conducted with the maximum respect for participants, their privacy while maintaining confidentiality

Questions?