Case Study Registration Process

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BRIEF ANNOUNCEMENTS

1. Today's presentation is being recorded
    - Visit the UNE Responsible Conduct of Research Training website to access the recording
2. Please hold all questions until the end of the presentation
3. Content is applicable to all UNE faculty, staff, and students regardless of college affiliation
4. PDF of the slide deck is available upon request (e-mail irb@une.edu)

LEARNING OBJECTIVES

1. Understand the definition of a case study
2. Recognize when a case study requires registration at UNE
3. For case studies that require registration, know when HIPAA authorization and/or patient consent is required
4. Understand how to submit an application for case study review

What is a case study?

CASE STUDY SPECIFICS

- A retrospective clinical analysis that summarizes a patient's symptoms, diagnosis, treatment, and/or follow-up
- Typically involves no more than 3 patients representing the same clinical presentation
- Used to develop information to be shared for medical or educational purposes via presentation or publication
- Often depict unique or rare clinical presentations

What circumstances require a case study to be registered at UNE?

CASE STUDY SPECIFICS

Workforce: Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the control of such covered entity whether or not they are paid by the covered entity

Registration REQUIRED

- If you intend to discuss or share a case study with individuals ***outside the workforce of the HIPAA covered entity***
- Registration must be obtained ***prior to the case study publication or presentation***

Covered Entity: A health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic format

UNE Covered Entity Components

- Coleman Dental Hygiene Clinic
- Student Health Care (Petts Health Center & Portland Health Center)
- MatureCare
- Oral Health Center

UNE has…

- 1 covered entity; and
- 1 workforce (comprised of 4 designated health care components)

EXAMPLES WHEN CASE STUDY REGISTRATION IS REQUIRED

- Prior to a case study being published in a medical journal, textbook, or other educational publication
- Prior to COM students presenting a case study at the UNECOM Research & Scholarship Forum or NEOMEN meeting
- Prior to presenting a case study of a patient treated at a UNE covered entity component and the audience will include individuals who are not part of the UNE covered entity workforce

What circumstances would NOT require a case study to be registered at UNE?

CASE STUDY SPECIFICS

Case studies are often discussed or shared as part of routine health care operations to improve future patient care and/or to educate/train the workforce

Registration NOT Required

- If you discuss or share a case study only with individuals ***within the workforce of the HIPAA covered entity***

Because…

- Sharing medical knowledge, improving quality, and/or providing education is part of routine *health care operations* as defined by HIPAA (45 CFR 164.501)

Examples of Health Care Operations

- Conducting quality assessment & improvement activities, including outcome evaluation & development of clinical guidelines
- Reviewing the competence or qualifications of health care professionals
- Evaluating practitioner and provider performance
- Conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers

Is a case study considered to be research?

CASE STUDY SPECIFICS

Definition of 'Research'

- "A *systematic investigation*, including research development, testing, and evaluation, *designed to develop or contribute to generalizable knowledge*"

Analysis

- Case studies (n≤3) do not meet the federal human subjects protection regulations definition of 'research'
- They are not deemed to be a systematic investigation; and
- Due to their small sample size, case studies are not designated to be predictive of similar circumstances

Do I need to obtain HIPAA authorization and/or patient consent for case studies that require registration?

CASE STUDY SPECIFICS

HIPAA Authorization

- Written authorization is required if the case study contains any of the 18 HIPAA identifiers
- Authorization should be sought from the patient or the patient's personal representative ***before the patient's PHI is disclosed outside of the HIPAA covered entity as part of the published or presented case study***

Patient Consent

- The clinician is strongly encouraged to obtain written consent from the patient or the patient's personal representative ***before the case study is published or presented to an audience outside of the HIPAA covered entity***
- Many journals require prospective patient consent be obtained as a prerequisite for publication

Note: Ignoring this requirement can result in rejection from the publisher, or worse – ruin your relationship/reputation with the patient

What are the 18 HIPAA identifiers?

18 HIPAA IDENTIFIERS

When a case study describes a unique or rare circumstance, it may be difficult or impossible to de-identify the case such that there is no reasonable expectation that the patient can be identified. In such cases, HIPAA authorization is required.

1. Name
2. Address (all geographic subdivisions smaller than a state, including street address, city, county, and zip code)
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. E-mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/License numbers
12. Vehicle identifiers and serial numbers including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address
16. Biometric identifiers, including fingerprints and voiceprints
17. Photographic images – including full facial photographs and other comparable images
18. Any other unique identifying number, characteristic, or code that could identify an individual

What is the process for obtaining HIPAA authorization and/or patient consent for a case study when registration is required?

CASE STUDY SPECIFICS

- The patient should be approached by the treating clinician and asked to review, sign, and date a HIPAA authorization and/or patient consent form (where applicable)
- If the patient is unable to provide authorization/consent for themselves (e.g., patient is a minor, incapacitated, exhibits impaired decision-making capacity, deceased, etc.), the patient's personal representative should be identified and approached
- Visit the UNE IRB website to access case-study-specific templates for HIPAA authorization and patient consent

What is the process for submitting an application for case study review?

APPLICATION PROCESS

1. Visit the UNE IRB website to obtain a current copy of the application
2. Follow the directions outlined in the application
3. E-Mail the completed application and any required supplemental documents to irb@une.edu (do NOT send zip files!)
4. The IRB administrator will acknowledge receipt of your e-mail and will assign your submission an IRB number

CASE STUDY SPECIFICS

For 3 or fewer patients (n≤3)

- Complete an '*Application for Case Study Registration*' for administrative review
- CITI training is NOT required
- Case study is registered by the Office of Research Integrity

For 4 or greater patients (n≥4)

- Complete an '*Application for Exempt Research Projects*' for review
- CITI training is REQUIRED
- Exempt review conducted by the Office of Research Integrity

Referenced applications can be found on the UNE IRB website

Questions?