Application for Case Study Registration

APPLICATION INSTRUCTIONS:

1. Before completing this application, please review the **Case Study Frequently Asked Questions** outlined in **Appendix A**.
2. Submit your completed application along with any required supplemental documentation to irb@une.edu for review.

Contact the Office of Research Integrity at irb@une.edu for any questions you may have with regard to this application process.

Application Date:	Enter text
Case Study Title:	Enter text

A. APPLICANT & CASE STUDY MENTOR INFORMATION

Applicant's Name: Enter text		**You are**: ☐ Faculty ☐ Staff ☐ Student ☐ Resident	**UNE Center or College**:	Enter text
E-Mail:	Enter text		**UNE Program of Study**:	Enter text
Phone #:	Enter text			

Case Study Mentor's Name[1]: Enter text	**E-Mail**: Enter text	**Phone #**: Enter text

Name and location of the covered entity (e.g., medical institution) where the patient's health information is being collected:

Enter text

[1] A Case Study Mentor is required when the Applicant is a student.

B. CASE STUDY DETAILS & REQUIRED SUPPLEMENTAL DOCUMENTATION

1. Will the case study involve 3 or fewer patients?

☐ **Yes** *(proceed to Question 2)*

☐ **No** *(Ineligible for registration via this application process. Please contact the Office of Research Integrity at irb@une.edu for next steps.)*

2. Will you be able to fully de-identify the case study by removing all 18 HIPAA identifiers?

☐ **Yes** *(HIPAA authorization is NOT required; skip to Question 4)*

☐ **No** *(HIPAA authorization is REQUIRED; proceed to Question 3)*

B. CASE STUDY DETAILS & REQUIRED SUPPLEMENTAL DOCUMENTATION

3. Will you be able to obtain written HIPAA authorization from the patient or the patient's personal representative ***before* the case study is published or presented?** *(this question is applicable only when the case study contains any of the 18 HIPAA identifiers)*

☐ **Yes** *(attach a copy of the authorization with the name & signature of the patient/personal representative redacted or blacked out)*

☐ **No** *(explain why below)*

Enter text

4. Will you be able to obtain written consent from the patient or the patient's personal representative ***before* the case study is published or presented?** *(it is respectful to obtain prospective consent whenever possible)*

☐ **Yes** *(attach a copy of the consent form with the name & signature of the patient/personal representative redacted or blacked out)*

☐ **No** *(explain why below)*

Enter text

C. APPLICANT & CASE STUDY MENTOR SIGNATURES

The **Applicant** accepts responsibility for the case study, and confirms the information provided in this application is true and accurate.

Applicant Signature _____ Date _____

The **Case Study Mentor** agrees to provide appropriate education and supervision to the **Applicant** for the case study. *(required when the Applicant is a student)*

Case Study Mentor Signature _____ Date _____

Appendix A

Case Study Frequently Asked Questions

1. What is a case study?

A case study is a retrospective clinical analysis of one, two, or three patients (n ≤ 3). Case studies typically summarize the symptoms, diagnosis, treatment, and follow-up of an individual patient. They are used to develop information to be shared for medical or educational purposes with other providers and often depict unique or rare clinical presentations. A case study may be published (in print or electronic format) for others to read, and/or presented at a conference or other educational event.

2. What circumstances trigger the need for an '*Application for Case Study Registration*' to be submitted?

If you intend to discuss or share a case study with individuals ***outside the workforce of the HIPAA covered entity***, you MUST register the case study with the Office of Research Integrity. The application must be submitted ***prior to the case study publication or presentation***.

3. What circumstances would NOT require an '*Application for Case Study Registration*' to be submitted?

Often, case study activity involves sharing medical knowledge, improving quality, and providing education. These activities fall under the HIPAA definition of *health care operations* (45 CFR 164.501), which includes:

- *"Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, providing that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, [and] protocol development…*and
- *Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan 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, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities."*

Case studies that are discussed or shared only with individuals ***within the workforce of the HIPAA covered entity*** (as described above) do NOT require registration with the Office of Research Integrity.

Note: Workforce members presenting case studies for health care operations purposes should be mindful to use or share only the minimum necessary PHI for the purpose of the activity.

4. Is a case study considered to be research?

Typically, case studies involving the retrospective medical review of three patients or fewer (n ≤ 3) do not meet the federal human subjects' protection regulation definition of research because they are not deemed to be a systematic investigation designed to develop or contribute to generalizable knowledge. As case studies, by definition, have a very limited sample size, they are not designed to be predictive of similar circumstances and hence do not meet the generalizable requirement of the aforementioned definition of research.

Note: A case study involving the retrospective medical review of four or more patients (n ≥ 4) is NOT eligible for case study registration via this application process. Please contact the Office of Research Integrity at irb@une.edu for next steps.

Case Study Frequently Asked Questions

5. Is CITI training a requirement for case study registration?

No, CITI training is NOT required for case study registration.

6. When is HIPAA authorization required for a case study?

If the case study does NOT contain any of the 18 identifiers that cause medical information to be considered PHI under HIPAA, the case study is considered to be de-identified, and its publication or presentation does NOT require HIPAA authorization from the patient.

However, if the case study DOES include any of the 18 HIPAA identifiers, prospective HIPAA 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 a published or presented case study***.

Note: When a case study describes or discusses a very unique or rare circumstance, it may be difficult or impossible to fully de-identify the case. HIPAA authorization would generally be required in this instance.

7. What are the 18 HIPAA identifiers?

PHI includes any of the following 18 identifiers of the patient or of their relatives, employers, or household members, all of which MUST be removed to de-identify the case study. This is known as safe harbor de-identification.

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
    - ***This includes case studies involving circumstances or conditions rare enough that individuals with personal knowledge of the case could identify the patient***

8. What is the process for obtaining HIPAA authorization?

The patient or the patient's personal representative should be approached by the treating clinician and asked to review, sign, and date a HIPAA authorization form. The signed authorization will allow the clinician to disclose the patient's PHI outside of the HIPAA covered entity in the case study publication or presentation. HIPAA authorization should be obtained ***before the case study is published or presented***.

Case Study Frequently Asked Questions

In the event the patient is unable to provide authorization for themself (e.g., patient is a minor, incapacitated, exhibits impaired decision-making capacity, deceased, etc.), the patient's personal representative should be identified and approached to provide HIPAA authorization.

When possible, the treating clinician should access the appropriate HIPAA authorization form provided by the covered entity. If the covered entity does not have a specific case study HIPAA authorization form for use, the treating clinician may use the modifiable '***HIPAA Authorization Template for Case Study***' document available on the UNE IRB website with permission from the covered entity.

Note: The patient or the patient's personal representative should be provided a copy of the signed HIPAA authorization form for their records.

9. Should prospective consent be obtained for a case study?

Yes, it's respectful to do so whenever possible. Many journals require prospective patient consent be obtained as a prerequisite for case study publication.

Note: Ignoring this requirement can result in rejection from the publisher, or worse – ruin the treating clinician's relationship and/or reputation with the patient.

10. What is the process for obtaining consent for a case study?

The patient or the patient's personal representative should be approached by the treating clinician and asked to review, sign, and date a case study consent form. The signed consent form permits the clinician to publish or present the case study outside of the HIPAA covered entity as part of a scholarly activity. Consent should be obtained ***before the case study is published or presented***.

In the event the patient is unable to consent for themself (e.g., patient is a minor, incapacitated, exhibits impaired decision-making capacity, deceased, etc.), the patient's personal representative should be identified and approached to provide consent for the case study.

When possible, the treating clinician should access the appropriate case study consent form provided by the covered entity. If the covered entity does not have a specific case study consent form for use, the treating clinician may use the modifiable '***Consent Form Template for Case Study***' document available on the UNE IRB website with permission from the covered entity.

Note: The patient or the patient's personal representative should be provided a copy of the signed case study consent form for their records.