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| **INSTRUCTIONS**:1. Before completing this application, please review the **Case Study Frequently Asked Questions** outlined in **Appendix A**.
2. Submit your completed application with the required signatures and supplemental documentation (see **Sections D & E** of this application) 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 the application process.  |

|  |  |
| --- | --- |
| Application Date: | Enter text |
| Case Study Title: | Enter text |

| 1. **APPLICANT & CASE STUDY MENTOR INFORMATION**
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| --- |
| **Applicant’s Name**:Enter text | **You are**:[ ]  Faculty[ ]  Staff[ ]  Student[ ]  Resident | **UNE Center or College**: | Enter text |
| **E-Mail**: | Enter text | **UNE Dept. or Program of Study**: | Enter text |
| **Phone #**: | Enter text |
|  |
| **Case Study Mentor’s Name1**:Enter text | **E-Mail**:Enter text | **Phone #**:Enter text |
|  |
| **Name of the covered entity (e.g., medical institution) where the patient’s health information is being collected**:Enter text | **Location of the covered entity (e.g., Portland, ME) where the patient’s health information is being collected**:Enter text |
| **1** | A Case Study Mentor is required when the Applicant is a UNE student. |

| 1. CASE STUDY DETAILS
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| 1. Does the case study involve 3 or fewer patients?

[ ]  Yes *(proceed to Question 2 below)*[ ]  No *(Ineligible for case study registration. Please submit an ‘Application for Exempt Research Projects’ instead.)* |
| 1. How many patients does the case study include?

[ ]  1 patient[ ]  2 patients[ ]  3 patients |
| 1. Is the patient (or patients) of the case study living or deceased? *(select one response)*

[ ]  Living[ ]  Deceased[ ]  Case study involves both living and deceased individuals |
| 1. Which of the following attributes best describe the case study? *(select all that apply)*

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| [ ]  Rare disease or condition[ ]  Unusual presentation of disease[ ]  Unexpected event(s)[ ]  Unusual combination of diseases or conditions[ ]  Difficult or inconclusive diagnosis | [ ]  Treatment or management challenges[ ]  Personal impact[ ]  Observations that shed new light on a disease or condition[ ]  Anatomical variations[ ]  Other *(describe below)* |

Enter text |
| 1. Do you intend to present or publish the case study? *(select one response)*

[ ]  Presentation only[ ]  Publication only[ ]  Both presentation and publication |
| 1. Will (or does) the case study contain any of the following HIPAA identifiers about the patient, or the patient’s relatives, employers, or household members?

[ ]  No [ ]  Yes *(Select all that apply in the table below. Written HIPAA authorization MUST be obtained. Follow the procedure outlined in Appendix A: FAQ #9.)*

|  |  |
| --- | --- |
| [ ]  **1**. Name[ ]  **2**. Address (all geographic subdivisions small than state, including street address, city, county, and zip code)[ ]  **3**. All elements of dates (except year) related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)[ ]  **4**. Telephone numbers[ ]  **5**. Fax numbers[ ]  **6**. E-mail addresses[ ]  **7**. Social security numbers[ ]  **8**. Medical record numbers (MRNs)[ ]  **9**. Health plan beneficiary numbers | [ ]  **10**. Account numbers[ ]  **11**. Certificate or license numbers[ ]  **12**. Vehicle identifiers and serial numbers including license plate numbers[ ]  **13**. Device identifiers and serial numbers[ ]  **14**. Web URLs[ ]  **15**. Internet protocol (IP) address[ ]  **16**. Biometric identifiers, including fingerprints and voiceprints[ ]  **17**. Full face photographic images and any comparable images[ ]  **18**. Any other unique identifying number, characteristic, or code that could identify an individual |

 |
| 1. Will (or does) the case study contain any information obtained from the patient’s medical record that appears in the table below?

[ ]  No *(Do not answer question 8 below. Proceed to section ‘C. Case Study Consent’.)*[ ]  Yes *(Select all items that apply in the table below. Then, proceed to question 8.)*

|  |  |
| --- | --- |
| [ ]  Demographic information (e.g., age, sex, gender, race, ethnicity, state of residence)[ ]  Psychosocial history (e.g., occupation, social support, education level)[ ]  Perinatal history (e.g., type of birth, length of pregnancy, if breast fed, and for how long)[ ]  Type of health insurance[ ]  Use of patient non-facial photographic images | [ ]  Environmental exposure (e.g., living and working environment, potential toxic exposures)[ ]  Lifestyle (e.g., sleep, stress management, exercise, recreational drug use, smoking, alcohol consumption, nutrition/diet)[ ]  Family medical history (e.g., if family members have similar conditions as the patient)[ ]  Genetic information (as relevant to the case)[ ]  Other potentially identifying details *(describe below)* |

Enter text |
| 1. Provide the rationale for why it was determined the case study does or does not require written HIPAA authorization.

*Note 1: A case study that includes information from the table in Question 7 may potentially include HIPAA identifier #18 which pertains to any unique characteristic that could identify an individual. For instance, if a case study discusses a rare disease/condition and contains indirect identifiers, it could lead to the identification of a patient.* *For example, if the case study provides details like ‘a 66-year-old Asian man living with rare disease X, residing in the state of Maine, a smoker, employed as a painter, and covered by Medicare insurance,’ this combination of indirect identifiers could potentially reveal the patient’s identity.**In such cases where the patient(s) could be reasonably identified in the case study presentation/publication based on the collected indirect identifiers, written HIPAA authorization is required.* *Note 2: If there is doubt about whether the combination of indirect patient identifiers included in the case study could reasonably identify the patient(s), the HIPAA Privacy Office at the institution where the patient(s) received treatment may be able to assist you with determining if written HIPAA authorization is necessary.*Enter text |

| 1. **CASE STUDY CONSENT**
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| 1. **Was a reasonable effort made to contact the patient/personal representative prior to case study presentation or publication?**

***Note****: When contact information is available, case study authors should make a reasonable effort to reach out to the patient/personal representative prior to case study presentation or publication to determine if obtaining consent is feasible. A ‘reasonable effort’ is defined as 2 to 3 communication attempts.*[ ]  **N/A** – contact information is not available[ ]  **Yes**[ ]  **No** *(explain why below)* Enter text |
| 1. **Was consent obtained from the patient/personal representative?** *(select all that apply)*

***Note****: Case study consent is not regulatorily required. However, it is respectful to obtain prospective consent from the patient/personal representative whenever feasible (even when the patient is deceased). Please follow the steps outlined in* ***Appendix A: FAQ #11*** *for obtaining case study consent.* [ ]  **Yes** – written consent was obtained[ ]  **Yes** – verbal consent was obtained[ ]  **No** *(explain why below)* Enter text |

| 1. REQUIRED SUPPLEMENTAL DOCUMENTATION CHECKLIST *(Do not send any zip files!)*
 | Yes | N/A |
| --- | --- | --- |
| 1. | When **HIPAA authorization** is required:* Attach a copy of the authorization form with the name & signature of the patient/personal representative redacted or blacked-out

**Note**: A modifiable ‘***HIPAA Authorization Template for Case Study***’ document is available for use on the UNE IRB [website](https://www.une.edu/research/integrity/irb). |[ ] [ ]
| 2. | When **written consent** has been obtained: * Attach a copy of the consent form with the name & signature of the patient/personal representative redacted or blacked-out

**Note**: A modifiable ‘***Consent Form Template for Case Study***’ document is available for use on the UNE IRB [website](https://www.une.edu/research/integrity/irb). |[ ] [ ]
| 3. | When **verbal consent** has been obtained: * Attach a copy of the verbal consent script with the name of the patient/personal representative redacted or blacked-out

**Note**: A modifiable ‘***Verbal Consent Script Template for Case Study***’ document is available for use on the UNE IRB [website](https://www.une.edu/research/integrity/irb). |[ ] [ ]

| 1. **APPLICANT & CASE STUDY MENTOR SIGNATURES** *(Typed signatures are NOT accepted!)*
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| --- |
| The **Applicant** acknowledges the regulatory (HIPAA) and ethical responsibilities involved with pursuing a case study, and confirms the information provided in this application is true and accurate.

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| 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)*

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| Case Study Mentor Signature |  | Date |

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**Appendix A**

| Case Study Frequently Asked Questions |
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| 1. What is a case study?

A case study (also known as a case report) is a detailed description of a clinical encounter with a patient. 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 health care professionals and often depict interesting, unique, or rare clinical presentations or events. 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.  |
| 1. Is there any industry guidance that outlines best practices for writing a case study?

Yes, case study authors are encouraged to review the CARE guidelines for writing a case study [here](https://www.care-statement.org/). The CARE guidelines (for CAse REports) were developed by an international group of experts to support an increase in the accuracy, transparency, and usefulness of case studies. Click [here](https://www.care-statement.org/checklist) to view and download the CARE checklist which outlines the recommended information to include when writing a case study. Click [here](https://www.care-statement.org/publications) to access the 2017 CARE checklist elaboration and explanation article, as well as view examples of published case studies that incorporate the CARE guidelines.  |
| 1. 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 (e.g., medical institution)*, you MUST register the case study with the Office of Research Integrity. The application must be submitted *prior to the case study presentation or publication*.  |
| 1. 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 *within the workforce of the HIPAA covered entity*. 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.  |

| Case Study Frequently Asked Questions |
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| 1. Is a case study considered to be research?

UNE considers a case study involving the retrospective medical review of three patients or fewer (n ≤ 3) to NOT meet the federal definition of research per 45 CFR 46.102 (*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*). Because case studies (n ≤ 3) have no predetermined hypothesis or research question, they do not trigger the ‘systematic investigation’ 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 submit an ‘*Application for Exempt Research Projects*’ to irb@une.edu for review instead.  |
| 1. Is CITI training a requirement for case study registration?

No, CITI training is NOT required for case study registration.  |
| 1. When is written 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 presentation or publication does NOT require written HIPAA authorization from the patient or the patient’s personal representative. However, if the case study DOES include any of the 18 HIPAA identifiers, written HIPAA authorization must be sought from the patient/personal representative *before the patient’s PHI is disclosed outside of the HIPAA covered entity as part of a presented or published case study*. Note: When a case study describes a very rare disease/condition, it may be difficult or impossible to fully de‑identify the case. In these instances, a consultation with the HIPAA Privacy Office (at the covered entity where the patient received treatment) is recommended to determine if written HIPAA authorization is required. |
| 1. 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 (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
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
 | 1. Certificate/License numbers
2. Vehicle identifiers and serial numbers including license plate numbers
3. Device identifiers and serial numbers
4. Web universal resource locators (URLs)
5. Internet protocol (IP) address
6. Biometric identifiers, including fingerprints and voiceprints
7. Full face photographic images and any comparable images
8. Any other unique identifying number, characteristic, or code that could identify an individual
* ***This includes case studies involving diseases or conditions rare enough that individuals with personal knowledge of the case could identify the patient***
* ***A combination of indirect identifiers detailed in a case study could potentially trigger HIPAA identifier #18***
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| Case Study Frequently Asked Questions |
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| 1. What is the process for obtaining written HIPAA authorization?

The patient/personal representative should be approached and asked to review, sign, and date a HIPAA authorization form. The signed authorization will allow the case study author to disclose the patient’s PHI outside of the HIPAA covered entity in the case study presentation or publication. HIPAA authorization should be obtained *before the case study is presented or published*. In the event the patient is unable to provide authorization 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 to provide HIPAA authorization. The following table displays who must be recognized as the personal representative when the patient cannot provide authorization for themselves:

|  |  |
| --- | --- |
| **If the patient is:** | **The personal representative is:** |
| An adult, or An emancipated minor | A person with **legal authority** to make health care decisions on behalf of the patient.***Examples***: health care power of attorney, court appointed legal guardian, general power of attorney or durable power of attorney that includes the power to make health care decisions***Exceptions***: See abuse, neglect, and endangerment situations as discussed [here](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html).  |
| An unemancipated minor | A parent, guardian, or other person acting in loco parentis (in place of a parent) with **legal authority** to make health care decisions on behalf of the minor child.***Exceptions***: See parents and unemancipated minors, and abuse, neglect and endangerment situations as discussed [here](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html). |
| Deceased | A person with **legal authority** to act on behalf of the decedent (deceased patient) or the estate *(not restricted to persons with authority to make health care decisions)*.***Examples***: Executor or administrator of the estate, next of kin or other family member (if state law provides authority).***Note***: HIPAA safeguards an individual’s PHI for 50 years following their death.  |

When possible, the case study author 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 case study author may use the modifiable ‘*HIPAA Authorization Template for Case Study*’ document available on the UNE IRB [website](https://www.une.edu/research/integrity/irb) 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.  |
| 1. Should prospective consent be obtained for a case study?

Although not regulatorily required, it’s respectful to obtain consent whenever feasible (even when the patient is deceased). The case study author should make a reasonable effort to contact the patient/personal representative *before case study presentation or publication* to determine if obtaining consent is feasible. A ‘reasonable effort’ is defined as 2 to 3 communication attempts. Note: Many journals require prospective consent be obtained as a prerequisite for case study publication (and the journal may also request that consent be documented using the journal’s specific case study consent template). Ignoring this requirement can result in rejection from the journal editor.  |
| 1. What is the process for obtaining consent for a case study?

Consent may be obtained via a written or verbal process (see details below). Obtaining consent from the patient/personal representative permits the case study author to present or publish the case study outside the medical institution as part of a scholarly activity. Consent should be obtained *before the case study is presented or published*.

|  |  |
| --- | --- |
| **Written Consent** | **Verbal Consent** |
| Written consent should be obtained when:* In-person, physical interaction with the patient/personal representative is feasible.
* Written HIPAA authorization is required.
* There is an intent to publish the case study. Many journals require prospective written consent prior to publication.

Steps for obtaining written consent:1. When possible, access the appropriate case study consent form provided by the medical institution. If the institution does not have a specific case study consent form for use, the case study author may use the modifiable ‘***Consent Form Template for Case Study***’ document available on the UNE IRB [website](https://www.une.edu/research/integrity/irb).
2. Draft the case study consent form.
3. Discuss the content of the case study consent form with the patient/personal representative in-person.
4. Address any questions/concerns from the patient/personal representative.
5. Ask the patient/personal representative to sign and date the case study consent form.
6. Provide a copy of the signed case study consent form to the patient/personal representative for their records.
 | Verbal consent should be obtained when:* In-person, physical interaction with the patient/personal representative is NOT feasible but contact information exists (e.g., patient was discharged from the hospital but could be reached by phone).
* Written HIPAA authorization is not required.

Steps for obtaining verbal consent:1. Access the modifiable ‘***Verbal Consent Script Template for Case Study***’ document available on the UNE IRB [website](https://www.une.edu/research/integrity/irb).
2. Draft the case study verbal consent script.
3. Contact the patient/personal representative (e.g., phone, Zoom) and follow the verbal consent script.
4. Address any questions/concerns from the patient/personal representative.
5. Document responses from the patient/personal representative as prompted within the verbal consent script document.
6. If requested, provide a written summary of the consent conversation to the patient/personal representative for their records.
 |

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. The following table displays who should be recognized as the personal representative when the patient cannot provide consent for themselves:

|  |  |
| --- | --- |
| **If the patient is:** | **The personal representative is:** |
| An adult, or An emancipated minor | A person with **legal authority** to make health care decisions on behalf of the patient. ***Examples***: health care power of attorney, court appointed legal guardian, general power of attorney or durable power of attorney that includes the power to make health care decisions |
| **If the patient is:** | **The personal representative is:** |
| An unemancipated minor | A parent, guardian, or other person acting in loco parentis (in place of a parent) with **legal authority** to make health care decisions on behalf of the minor child |
| Deceased | A person with **legal authority** to act on behalf of the decedent (deceased patient) or the estate *(not restricted to persons with authority to make health care decisions)*.***Examples***: executor or administrator of the estate, next of kin or other family member (if state law provides authority)***Note***: In the event a personal representative with **legal authority** (as outlined above) cannot be identified and/or contacted, consent may not be required so long as the case study is appropriately de‑identified. However, some journals may still mandate that written consent be obtained prior to publication.  |

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