UNIVERSITY OF NEW ENGLAND

OFFICE OR RESEARCH INTEGRITY **INSTITUTIONAL REVIEW BOARD**

HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED

INSTRUCTIONS FOR COMPLETING THE REGISTRATION OF CASE STUDY FORM

Provide the Author's name and contact information in the first section, as well as the Faculty Mentor's name and email, if necessary. Provide the Facility Name (*e.g.* hospital or clinic name) and Case Study Title.

Question 1: Answer based on the *total* number of patients involved in the case study.

Question 2: Answer based on whether you are receiving access to, or being given copies of, Protected Health Information from a Covered Entity.

Question 3: Answer based on whether the records or data you will access have any of the 18 HIPAA identifiers.[1] Note that this question deals with access to data, not the data you plan to collect. For instance, if you are given access to a patient chart or EMR with any of the 18 HIPAA identifiers, your answer to this question will be "yes" and you will go on to question 4. If you are being given a deidentified set of data points, or a chart or EMR redacted so that none of 18 HIPAA data points are present, you will answer this question "no" and go on to the signature blocks.

Question 4: If you answer "Yes" to Question 4, provide a blank, unexecuted copy of the HIPAA authorization or Consent Form the Covered Entity provided to patients at the time the PHI was created. If you answer "No" to Question 4, follow the link in the form to download and prepare a "UNE Request for Approval to Use Protected Health Information" form.

[1] The 18 HIPAA identifiers are:

1. Name
2. Address (all geographic subdivisions smaller than 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 number
6. Email address
7. Social Security Number
8. Medical record number
9. Health plan beneficiary number
10. Account number
11. Certificate or license number
12. Vehicle identification numbers, serial numbers or license plates
13. Device identifiers and serial numbers
14. Web URL
15. Internet Protocol (IP) Address
16. Biometric identifiers, including finger or voice print
17. Photographic image - Photographic images are not limited to images of the face.
18. Any other characteristic that could uniquely identify the individual.
    i. This includes reports involving circumstances or conditions rare enough that individuals with personal knowledge of the case could identify the patient.

Once the form is complete and signed, please submit the for to **IRB@une.edu**

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CASE STUDY REGISTRATION FORM

Name:	Email:	Are you: ☐ Faculty ☐ Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Other
Address:		Department:
Faculty Mentor:	E-mail:	
Facility Name:	Case Study Title:	

1. Does this case study/ retrospective chart review involve fewer than 5 patients (*n*<5)? ☐ Yes (Please answer 2) ☐ No (Ineligible for registration, prepare Application for Exemption or Application for Review)	**2. Will this study involve the access to or transfer of protected health information (PHI) from a covered entity, as defined under HIPAA, to you?** ☐ **Yes (If yes, continue to number 3)** ☐ **No (If no, continue to signature block)**
3. Will the case study be fully deidentified by removing all 18 HIPAA identifiers from the final report? ☐ **Yes (If yes, continue to signature block)** ☐ **No (If no, continue to number 4)**	**4. Have all patients provided a written HIPAA authorization permitting use of their PHI in research and scholarly activities?** ☐ **Yes (If yes, *provide a copy of the authorization form the Covered Entity uses &* continue to signature block)** ☐ **No (If no, prepare a Request for Approval to use Protected Health Information)**

SIGNATURES

The registration will not be processed until all signatures are obtained.		
Signature of Principal Investigator The undersigned accept(s) responsibility for the study, and represents that the foregoing information is true and accurate		
Print Name of Principal Investigator:	**Signature of Principal Investigator:**	**Date:**

Signature of Faculty Research Supervisor – Required for Student Research By signing this form, the faculty research supervisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator, above.		
Print Name of Faculty Supervisor:	**Signature of Faculty Supervisor:**	**Date:**

UNE IRB Submission Requirements

- **Only complete submissions to the IRB will be registered.** ***Please ensure that each registration includes all documents requested in Box 4, if applicable.*** **Submit the completed registration electronically to IRB@une.edu** and to either The Associate Dean for Research (COM case studies only; Dr. Carol Brenner cbrenner1@une.edu; 207-602-5977); or Amy LItterini, DPT, (Physical Therapy case studies conducted outside PTH 608/708 only; alitterini@une.edu; 207-221-4586).

- PDF.pdf format is required, including scanned signatures.

UNE IRB
IRB@UNE.EDU

Questions? Please call: (207) 602-2244
E-mail: IRB@UNE.EDU