**UNE GUIDANCE REGARDING CASE STUDIES AND**

**IRB REVIEW[[1]](#footnote-1)**

Federal regulations and UNE policy require prospective Institutional Review Board (IRB) approval for **all** research involving human subjects. This requirement applies to all UNE faculty, staff or students. IRB review needs to take place **before** the research activity begins. The IRB cannot grant retrospective approval once a research project is complete. Failure to obtain IRB review may mean you are unable to publish or present your research. Err on the side of caution and either submit an application or contact the IRB at [irb@une.edu](mailto:irb@une.edu) or 207.602.2244. All necessary forms are at <https://www.une.edu/research/compliance/irb>.

UNE has adopted the following guidance for managing case studies in terms of IRB review. Please note that this guidance only applies to retrospective case studies and only addresses IRB review of case studies that are conducted either a) at UNE or b) in connection with any educational, scholarship or employment requirements applying to any UNE student, staff or faculty member.

This guidance does **not** waive any requirements for HIPAA review of access to protected health information. Nor does it affect any other institution’s requirements relating to IRB review or HIPAA privacy practices.

If you have registered your case study, and a journal requests proof of IRB review, please notify the Director of Research Compliance. You will receive a letter outlining this guidance, which you can submit to the journal.

**Guidelines**

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| PUBLICATION ACTIVITY | IRB REQUIREMENTS | HIPAA REQUIREMENTS |
| Case report/retrospective chart review involving fewer than 5 patients (*n*<5) | No IRB review is required. Register the review with the Associate Dean for Research (COM case studies); Amy Litterini, (Physical Therapy case studies done outside PTH 608/708); and the UNE IRB using the Case Study Registration Form. | A case study that includes 1 or more of the 18 HIPAA identifiers will require an authorization for disclosure of PHI in the final case report. This includes cases or conditions so rare that individuals with personal knowledge of the case could identify the patient. Questions regarding HIPAA authorizations should be addressed to the appropriate HIPAA privacy officer, either at UNE or at the facility which treated the patient.  Patients must provide a written HIPAA authorization in order for their PHI to be included the case report. Written authorization is not required if the case study is fully de-identified in accordance with 45 CFR 164.514(a) |
| Case report/retrospective chart review involving 5 or more patients (*n* ≥5) | IRB review required. Prepare [Application for Exemption](https://www.une.edu/pdfs/application-exemption) unless population includes a prisoner or involuntarily committed/hospitalized person, in which case prepare [Application for Initial Review and Approval](https://www.une.edu/pdfs/irb-application-initial-review-approval). | Written HIPAA authorization must be obtained unless the IRB has granted a waiver of authorization and/or documentation of informed consent. *See*, [Request for Approval to use Protected Health Information](https://www.une.edu/pdfs/application-approval-use-phi) |
| Series of case reports/retrospective chart reviews involving 5 or more patients in aggregate (*n* ≥5) | IRB review required. Prepare [Application for Exemption](https://www.une.edu/pdfs/application-exemption) unless population includes a prisoner or involuntarily committed/hospitalized person, in which case prepare [Application for Initial Review and Approval](https://www.une.edu/pdfs/irb-application-initial-review-approval). | Written HIPAA authorization must be obtained unless the IRB has granted a waiver of authorization and/or documentation of informed consent. *See*, [Request for Approval to use Protected Health Information](https://www.une.edu/pdfs/application-approval-use-phi) |

1. Based on materials from University of Alabama [↑](#footnote-ref-1)