



Guidance for Case Reports

Background

To ensure compliance with regulations governing research with human subjects and the HIPAA Privacy Rule, the Human Research Protection Program (HRPP) provides the following guidance for Case Reports.

Overview

If you are including one, two, or three cases in your report (known as a “Single Case Report” or “Limited Case Series”), then the analysis is not “a systematic investigation designed to develop or contribute to generalizable knowledge” and thus does not meet the federal definition of research. Instead, it is shared for medical and educational purposes. However, HIPAA regulations apply to this work because you are using Protected Health Information (PHI). A waiver of HIPAA authorization does not apply to case reports because the Privacy Rule limits such waivers to research. It is common for journals to require HIPAA authorization from patients whose cases are described in submitted articles.

Additionally, many journals require documentation of an IRB determination for case reports. The IRB cannot make retroactive determinations. Therefore, Case Reports involving three or fewer cases should still be submitted in IRBManager for a formal “not human subjects research” (NHSR) determination. Failure to obtain a prospective determination may prevent you from publishing.

If you are including more than three cases in your report, then your project *does* meet the federal definition of research, and you must submit to the IRB for review using the “New IRB Research” xForm.

Written authorization is required in the following scenarios

- When the author intends to publish case report data with HIPAA identifiers.
- When the case report, even after de-identification, includes unique characteristics which could identify the patient (e.g., rare diseases or circumstances).
- When the author knows or has reason to believe that the information, either alone or combined with other data, could be used to identify the patient.

Additional Considerations

- In situations where authorization cannot be obtained, authors should reach out to the privacy office at privacyoffice@utoledo.edu. The IRB does not make determinations regarding the requirement to obtain HIPAA authorization. Questions can be directed to the Privacy Office at privacyoffice@utoledo.edu.
- The HIPAA authorization form, also referred to as case report consent, can be obtained on the Privacy Office's [webpage](#).
- A copy of the signed HIPAA authorization form must be added to the patient's medical records.
- For guidance on the removal of HIPAA identifiers, refer to [Guidance for Removal of Individual Identifiers from Information/Records/Samples](#).