Human Research Protection Program
R1 Building, Mail Stop 218
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IRB.Biomed@utoledo.edu | 419-383-6796
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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 IRB determination for case reports. The IRB cannot make retroactive determinations. Therefore, Case Reports involving three or fewer cases should be submitted the IRB 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 and approval.

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Written HIPAA 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 HIPAA authorization cannot be obtained, authors should reach out to the privacy office at privacyoffice@utoledo.edu. The IRB cannot make an NHSR determination until the Privacy Office has made a determination whether HIPAA authorization is required.
- 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 Health and Human Services' guidance on deidentification.