

Case Reports and Case Series

Definitions

Case report/series - a detailed report of the diagnosis, treatment, and follow-up of an individual patient. Case reports may also contain some demographic information about the patient (for example, age, gender, ethnic origin).

Research – a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45CFR46.102(d))

Case reports and IRB review

Case reports are retrospective analyses of a single outcome. A single case report does not meet the definition of research. Health Information Management may need to review the activity for patient privacy and confidentiality. Prospective research that involves just a single subject does not qualify as a case report just because the research is limited to one individual.

Although there is no requirement for IRB approval for a case report, the HIPAA Privacy Rule restricts how protected health information (individually identifiable health information) may be used and disclosed. HIPAA requires written authorization for certain uses and disclosures of an individual's protected health information, including publication of a single case report.

Case series and IRB review

A case series may require a determination from the IRB. The IRB usually excludes case series of five or fewer patients from requiring review. Case series with six or more cases must be submitted to the IRB as research or for a determination that it does not meet the definition of research. The rationale for this requirement is that case series involving greater than five records frequently involves dozens of records and could be more appropriately classified as descriptive or observational research.

Obtaining patient authorization

In a situation of a case report or case series including a facial photograph, another type of image showing a unique identifier, or reporting a case so unique that the identity of the subject(s) would be readily known upon publication review by Health Information Management before proceeding with presentation or publication will be required. Patient authorization may be required to present or publish the case series. A researcher may be exempted from obtaining a signed authorization from the patient discussed in the case report if certain identifiers are removed from the case report prior to disclosure.

If a patient is deceased, authorization for the use of identifiable patient information must be obtained from the personal representative of the patient's estate.