

Case Reports

Overview:

A case report or case study consists of medical history and other relevant information initially collected to analyze and diagnose a patient's condition or for instructional purposes. The collection of data can be from a single patient or a small number of patients. Although there is not complete agreement on how many patients can be included in a case report, many institutions have limited them to no more than 3 or 4 patients. If you plan to include more than that number, please consult with the IRB. Because this information was not collected with any intent to test hypotheses or otherwise produce 'generalizable' knowledge, the activity does not meet the criteria for 'research' ([45 CFR 46.102\(d\)](#)), and ordinarily does not require IRB oversight.

However, when clinicians explicitly seek out an individual with a particular condition or medical anomaly, and the intent of the publication is to generalize the outcomes, test explicit hypotheses, and/or evaluate the condition in a planned, systematic manner, these activities may meet criteria for research that requires IRB oversight. Under these circumstances, the clinician should submit a research proposal to the IRB before embarking on additional data collection or analyses.

Considerations:

- Although publishing a case report may not require submission to the IRB, investigators should be aware of the use of individually identifiable health information in their publications. Under HIPAA, the disclosure of an individual's protected health information must be authorized by that individual. In other words, if a case report contains any identifiers as defined by the HIPAA regulations, authorization to disclose this information in a publication must be sought from the individual whose information is being disclosed.
- If you are unsure whether your project requires IRB review, <mailto:askirb@pitt.edu> or call the Main IRB Office at 412-383-1480.