Creighton UNIVERSITY
Institutional Review Board

Case Study or Human Subjects Research?

Determining whether a case study[1] or series meets the definition of human subjects research is not always straight forward. For multi-case projects, there is no "magic number" of cases under which you can definitively conclude a project is not human subjects research. Generally speaking:

- Descriptive case studies which are published and/or presented at national or regional meetings are not considered research if the case is limited solely to a description of the clinical features and/or outcome of individual patients.
- If, however, a case study involves multiple patients with concomitant analysis and correlation of data as part of a systematic investigation, it is considered research. Depending on whether subject identifiers are maintained, it may qualify as exempt research.

Case studies that are not considered research do not need to be submitted to the IRB unless the Principal Investigator wants a Not Human Subjects Research (NHSR) determination letter from the IRB for purposes of publication or presentation.

IMPORTANT: As with all other research and non-research submissions to the IRB, case study proposals must be submitted to the IRB for review before case study analysis begins. This applies to case studies/series which are for publication or presentation only. The IRB is unable to issue a retroactive NHSR determination

The checklist below will help determine whether a project is a case study (NHSR) or human subjects research, which will yield generalizable knowledge. If YES is the answer to any of the questions listed, this indicates that a project may involve human subjects.

	YES	NO
Will you be comparing/contracting cases (as opposed to merely presenting the case(s))?		
Does the project include statistical analysis?		
Do you have a hypothesis?		
Does the case study pertain to a rare disease such that information on a solitary case might be generalizable?		
If you will utilize the patient's medical records to complete the case report, will you need to request access to the records because you don't already have access to the medical records?		
If you will be interviewing the patient(s) for your case report, do your interview questions include those likely to yield generalizable information (ex. "What would you recommend?")?		

[1] When a physician or other healthcare professional authors a case history that is not research, ethical guidelines should, nevertheless, be taken into consideration; specifically, informed consent should be obtained from the patient and appropriate safeguards to protect confidentiality should be in place.

This guidance is adapted with permission from University of Nebraska Medical Center.