



Case Studies and Reports

*Based on guidance from Boston University Medical Campus and Boston Medical Center IRB and
LSU Health New Orleans IRB*

Case studies typically involve the collection and presentation of detailed information about a particular patient/person or small group to highlight an interesting condition, treatment, presentation or outcome.

To determine whether a case study or case series requires IRB review, recall the definition of human subjects research; specifically, that it is designed to contribute to generalizable knowledge. A case study, in contrast, tends to highlight one or a few particular cases for purposes of demonstration rather than for purposes of drawing generalized conclusions. Below are some criteria that tend to be representative of either case studies or research; this list is to be used as a guide not as a definitive determination.

Case Study:

- Report on 3 or fewer subjects
- Not meant to be a representative sample (not drawing conclusions)
- Reported/Published without attempting to draw broader conclusions

Research:

- Report on more than 3 subjects
- Drawing conclusions about a broader population based on the reported cases (even if not statistically significant; e.g. pilot studies can be "research")
- Reported/Published in a way that suggests broad findings or recommendations

A **case report** is a detailed report of the diagnosis, treatment, response to treatment, and follow-up after treatment of an individual patient. A case series is group of case reports involving patients who were given similar treatment. Case reports and case series usually contain demographic information about the patient(s), for example, age, gender, ethnic origin. When information on **more than three patients** is included, the case series is considered to be a systematic investigation designed to contribute to generalizable knowledge (i.e., *research*), and therefore submission is required to the IRB.

For **all** case reports and case series, a signed HIPAA authorization should be obtained from the patients or their legally authorized representatives for the use and disclosure of their Protected Health Information. The only exception to the requirement for obtaining authorization is if the author of a case report or case series believes that the information is not identifiable; in this



case, the author must consult with the University of Montana HIPAA Privacy Officer to seek an expert opinion about the magnitude of the risk of identifying an individual. Please note that for deceased patients, authorization must be obtained from the personal representative, who is the administrator or executor of the patient's estate.

For case reports or case series containing more than three patients, the HIPAA authorization should be part of the consent form that is reviewed by the IRB.