



IRB Toolbox

IRB Review of Case Studies

Case studies generally involve the collection and presentation of detailed information about a particular participant or small group to highlight an interesting condition, treatment, presentation or outcome. When considering a case study, one of your first questions should be: does this study need IRB review? The approach to this question is the same as that for any study involving human subjects. The researcher must first answer the question: Does my study meet the definition of research?

What constitutes “research”?

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

A single retrospective case study that reports the observation of a single subject receiving the normal standard of care (no new or novel procedures) is generally not considered research. There is no intent to test a hypothesis via systematic analysis, or add to a body of knowledge.

However, when a series (more than one) of subject observations is compiled in such a manner that would allow possible extrapolation of the results to a larger population, this would likely represent research.

What to do?

At OSU, the decision if a proposed case study meets the definition of research should be made in concert with the IRB, either through discussions or via submission of the Determination of Non-Human Subject or Non Research form (<http://compliance.vpr.okstate.edu/hsp/NonHumanNonResearch%20form.doc>). Whether IRB review is required or not, care must be taken to protect the confidentiality of the subject’s private information, including compliance with any requirements of the Health Insurance Portability and Accountability Act (HIPAA).

For more assistance please call or come by the IRB Office located in the Office of University Research Compliance, 223 Scott Hall, 405.744.3377 or irb@okstate.edu.

