DHA Human Research Protections Program

Issue: Case Studies and Requirements for Review

Case studies are common, especially in the clinical setting. They frequently focus attention on a single individual, or a small group of similarly-situated individuals displaying a new/interesting condition or behavior. The aim of these types of studies is to provide education, and, perhaps a springboard for new areas of inquiry. Therefore, the question is:

This paper will seek to address that question from the perspective of the Defense Health Agency (DHA) Human Research Protections Program (HRPP).

Regulatory Definition:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Section 219.102(d) of Reference (a)) (emphasis added)

Are Case Studies Considered "Research" Subject to the Common Rule?

In general, case studies involving no more than three (3) subjects are not considered research, because such limited analyses are typically not *systematic investigations*, so the Common Rule does not apply. It is advisable to consult with the DHA Human Research Protections Program (HRPP) Office (or your local HRPP representative) before initiating the study. If an investigator will seek to publish the case study, then journals and professional organizations that sponsor conferences often require a formal determination that the activity is/is not research involving human subjects. If the activity is considered research involving human subjects, then the formal determination must note that the study protocol is compliant with the Common Rule.

Are Case Studies Subject to Other Regulatory Requirements?

Even though the Common Rule may not apply, other Federal regulations might (*e.g.,* the Health Insurance Portability and Accountability Act (HIPAA)); therefore, it is important that investigators consult with local privacy officials to determine if additional requirements must be met before initiating the study. It is not uncommon for there to be "use or disclosure" of protected health information in clinical case studies. In those cases, the HIPAA Privacy Rule regulatory requirements could well apply. ***In any case, it is always good practice to obtain Authorization from participants in case studies.***

References

(a) Title 32 Code of Federal Regulation Part 219, *Protection of Human Subjects*
(b) DoD Instruction 3126.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research", November 8, 2011

Resources

HHS Office for Human Research Protection: http://www.hhs.gov/ohrp/
DHA Human Research Protection Program: https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Protect-Humans-in-Research
DHA Privacy and Civil Liberties Office: https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties
32 CFR 219: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title32/32cfr219_main_02.tpl
DoD Instruction on HRPP: http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf