This policy pertains to case reports in the field of medicine and related clinical fields. Outside of medicine the “case report” may have different meanings and this policy does not pertain to those situations.

Case reports are medical information collected and presented on a single patient. Case reports are done to highlight a unique treatment, a unique case, or a unique outcome. They present clinical information on a single patient describing the treatment or outcome. Case reports are generally done by retrospective review of the medical record. Nothing is done to the patient for research purpose. Statistics are not used and the case report generally only describes existing clinical data or procedures.

While a case report does involve a human subject and may contribute to generalizable knowledge, a case report is not typically a systematic investigation and therefore does not meet the definition of research. Institutional Review Board (IRB) review is typically not required for a clinical case report on a single patient with no prior research intent. If more than one patient will be included in a case series, it may be considered research and require IRB review. If anything will be done in the course of care with a research intent, the case report may also become research. When a program or investigator plans to call a case report research or will use it to fulfill a research requirement, it may require IRB approval. In such instances, the policies and procedures in the Human Research Protection Program (HRPP) Manual 4-3 “Determination of Human Subject Research” will be followed to determine whether the activity is human subject research.

In most cases, the investigator must obtain Health Insurance Portability and Accountability Act (HIPAA) authorization to use the patient’s health information. In rare cases, the investigator may apply for a waiver of authorization to a privacy board, but it is generally determined authorization can be obtained. There are instances when human subjects are not involved in research but the activity requires privacy board review and determination (e.g. research involving deceased individuals). See HRPP Manual 5-7 “Privacy Board” for procedures related to HIPAA authorization and waiver.