SOUTHERN ILLINOIS UNIVERSITY CARBONDALE
Institutional Review Board

IRB Policy #:	**130**
Policy Title:	***Care Report Determinations***
Date Approved:	**December 9, 2022**
Date Reviewed:	**December 9, 2022**
Who must know:	**Principal investigators and key personnel approved to conduct human subjects research activities**

Purpose

The purpose of this document is to define case reports and describe the SIUC IRB policy for reviewing case reports.

Definitions

Case Report: For IRB purposes, a single case report is a retrospective analysis of one, two, or three clinical cases.

Investigator: Department of Health and Human Services (HHS) guidance uses the term "investigator" to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and/or studying, interpreting, or analyzing identifiable subject data.

Principal Investigator (PI): The "principal investigator" holds overall responsibility for the study. The Principal Investigator is responsible for the submittal of the proposed protocol, ethical design and conduct of protocol activities, and supervision of all study personnel.

Policy Statement

A single retrospective case report is a medical and/or educational activity and does not meet the Federal Policy for the Protection of Human Subjects definition of "research." HHS regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Case reports involving one, two, or three participants, with no prior research intent typically do not require SIUC Institutional Review Board (IRB) review. A protocol may require IRB review if it meets any of the following criteria:

- If more than three participants will be included in the case report,
- If a treatment will be performed for a purpose other than standard treatment,
- If a case report is called human subjects research by the investigator,

- If the case report will be used to fulfill a research requirement, such as a student capstone, thesis, or dissertation.

General Procedures

Formal determinations can only be issued if the investigator submits an IRB application. Upon review, if a retrospective analysis of one, two, or three case reports does not meet the criteria outlined in the policy, the IRB will issue a formal determination classifying the project as a case report. If, upon review, the project meets any of the above criteria, the IRB will review the submission as human subjects research.

Investigators are encouraged to contact the IRB with any questions about whether a project requires review.

References

U.S. Department of Health and Human Services. (2018). *Federal policy for the protection of human subjects 45 C.F.R. § 46.* https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

We would like to acknowledge the use of IRB guidelines from the University of Pennsylvania and Michigan State University when formulating this policy.