SIU SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Review Board Policy

IRB Policy #:	**130**
Policy Title:	***Case Report Determinations***
Date Approved:	**December 9, 2022**
Date Reviewed:	**December 9, 2022**

Purpose: The purpose of this document is to define case reports and describe IRB policy for handling case reports.

Definitions:

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

Policy:

A single retrospective case report is a medical/educational activity and does not meet the Federal Policy for the Protection of Human Subjects definition of "research" which is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Institutional Review Board (IRB) review is typically not required for a case report involving one, two, or three participants with no prior research intent but all PIs must submit an IRB application.

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 on the case subjects,
- If a case report is called research by the investigator,
- or if the case report will be used to fulfill a research requirement, such as a student project, thesis, dissertation, etc.

If a retrospective analysis of one, two, or three clinical cases does not meet the above criteria, a determination letter will be issued classifying it as a case report. If a retrospective analysis of one, two, or three clinical cases meets any of the above criteria, it will be reviewed as human subjects research.

I. Adapted from:

1. University of Pennsylvania Institutional Review Board, "Is IRB Review

Required?"
https://irb.upenn.edu/sites/default/files/Is%20IRB%20Review%20Required.pdf

2. HRPP Manual Section 4-3-A, Michigan State University
https://hrpp.msu.edu/help/manual/4-3-A.html