

SOP 408: MEDICAL CASE REPORTS

PURPOSE

This policy outlines the position of the University of Utah Institutional Review Board (IRB) regarding medical case reports.

SCOPE

This policy applies to activities that are considered medical case reports authored by University of Utah faculty or staff.

POLICY

If an author develops a case report with no prior research intent, the University of Utah IRB does not require review if the report does not meet the regulatory definition of research.

In many instances, case reports do involve a human subject(s) by definition, and may contribute to generalized knowledge by presentation or publication. A case report (3 or fewer patients) generally does not meet the definition of a systematic investigation. A case report describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.

PROCEDURES

1. The author of a case report must use the Case Report Using Existing Data - Author Worksheet available on the IRB website to determine whether new study application is necessary.
2. IRB review is not required if the author determines, using the worksheet, that the case report is not a systematic investigation. The author should retain a copy of the worksheet.
3. If the author is unable to determine, using the worksheet, that the case report is not a systematic investigation, IRB review is required. In this case, the author must submit a new study application to the IRB for review. A new study application may also be submitted if the author wishes to have the project reviewed by the IRB.
 - 3.1. If the report does not meet the definition of human research, the IRB will issue a letter confirming this determination.
 - 3.2. If the IRB administrator determines that the submitted proposal qualifies as research, the IRB will proceed with its review the project.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.