

Approved by IRB executive committee: June 6, 2007
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AAHRPP Element I.3.C

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 determine whether the IRB requires submission of a new study application by using the Case Report Using Existing Data - Author Worksheet found on the IRB website.
2. Submission for IRB review is not required if the author determines through the use of the worksheet that the case report is not a systematic investigation. The author should retain a signed copy of the worksheet.
3. Submission for IRB review is required if the author cannot determine through the use of the worksheet that the case report is not a systematic investigation. The author should submit a new study application to the IRB for review.
 - 3.1. If the report does not meet the definition of human research, the IRB will provide a letter that indicates such a determination.
 - 3.2. If it is the conclusion of the IRB administrator that the submitted proposal meets the definition of research, the IRB will review the project.
4. A new study application may be submitted if the author wishes to have the project assessed by the IRB. If a new study application is submitted, the IRB administrator will review the proposal. The author should attach a copy of the Case Report Using Existing Data - Author Worksheet.
 - 4.1. If the report does not meet the definition of human research, the IRB will provide a letter that indicates such a determination.
 - 4.2. If it is the conclusion of the IRB Administrator that the submitted proposal meets the definition of research, the IRB will review the project.