



Policy Name: **Case Reports Policy**

Section : HRPP 3.7

Effective Date: 02/20/2009

Replaces Policy: n/a

I. Policy

A. Introduction

In an academic medical center it is not unusual for unique and interesting clinical cases to be written up as case reports for publication in medical journals or presentation at medical or scientific meetings.

B. Scope

This policy clarifies whether case reports require IRB review and approval at the Medical University of South Carolina.

II. Regulations

A. The Federal Policy for the Protection of Human Subjects (45 CFR 46.102(d)) defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

B. Research requires IRB approval prior to be conducted.

III. Medical University of South Carolina Institutional Review Board Position

A. It is the policy that the publication of case reports of three or fewer patients is NOT considered human-subject research and does NOT typically require IRB review and approval because case reporting on a small series of patients does not involve the formulation of a research hypothesis that is subsequently investigated prospectively and systematically for publication or presentation. Therefore three or less case is not considered research but rather a clinical exercise.

B. A case series (more than 3) meets the definition of research.

C. If the journal requires a written statement, the IRB will send to the investigator a form letter that states:

“The IRB received your request (dated ‘x’), concerning a case report you wish to publish. The Medical University of South Carolina IRB has

determined that a case report (3 or fewer patients) does not produce generalizable knowledge, nor is it an investigation of an FDA regulated product. IRB review is not required for this activity.”

- D.** Confidentiality: Patient confidentiality should be respected in all clinical situations involving identifiable medical information from patients. All clinicians are reminded of the following:

Names, dates of birth, social security numbers, and other "codes" or combinations of identifiers, which might easily allow someone to identify a subject, should never be used in publications or external presentations.