IRB SOP 805
Case Studies/Reports

Purpose

Policy

If an author develops a case report with no prior research intent, the USA IRB does not require review if the report does not meet the regulatory definition of research. Federal regulations for the protection of human subjects define "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

In many instances, case reports do involve human subject(s) by federal definition, and may contribute to generalizable knowledge by presentation or publication. A case study/report or the retrospective review of medical records involving data from three or less patients does not involve a "systematic investigation" or contribute to "gendicti gemat635tumt12 ( )4 (g)2 (e)B ()9 5(e)3 (bt1 / r

consent, the specific authorization of the patient's legally authorized representative before submission for publication.

6.0 A case report involving three or fewer patients containing PHI that is presented outside the institution or submitted for publication does not constitute "research" under the HIPAA Privacy Rule and therefore does not qualify for a waiver of the HIPAA requirement for specific authorization of the patient.

7.0 The review of medical records involving four (4) or more patients constitutes "research" and requires IRB review and approval.

History:

Effective Date:
Revisions: October, 2018

Responsible Office:

Office of Research Compliance and Assurance