



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 805
Case Studies/Reports

Purpose

The purpose of this Standard Operating Procedure (SOP) is to document the procedures used the USA Institutional Review Board (IRB) to review and evaluate submissions for the use of case studies/reports.

Scope

This SOP applies to the IRB administrative staff, Board members and research investigators.

Applicability

Other than as required by the USA IRB, many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case.

Definitions

Case Report: A case report is a retrospective analysis of one, two, or three clinical cases. It describes an interesting treatment, presentation or outcome.

Protected Health Information (PHI) is individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for healthcare provided to an individual.

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 “generalizable knowledge.” Therefore, this activity does not require IRB review and approval, and has been given “not human subjects research” (NHSR) status by the IRB.

Although IRB review and approval is not required for case reports as described above, certain HIPAA Privacy Rule requirements may apply.

Procedures

- 1.0 USA research investigators who prepare a case report/study or who review medical records involving three (3) or fewer patients do not need to undertake any interaction with the IRB, as this activity has been designated “not human subject’s research” status.
- 2.0 If a case report involving three or few patients is prepared for publication or publication and does not contain one or more of the 18 identifiers enumerated in the HIPAA Privacy Rule, and does not review “unique characteristics” or otherwise allow for identification of the patient, then specific authorization of the patient is not required.
- 3.0 If a case report involving three or few patients containing PHI is presented a part of local educational programs within USA or affiliated institutions, then the activity is considered part of standard health care operations under HIPAA and may be presented without specific patient authorization.
- 4.0 If a case report involving three or fewer patients containing PHI is presented as part of an educational program conducted outside of USA or affiliated institutions, then the activity is not considered part of standard health care operations under HIPAA and may be presented only with a HIPAA-compliant, specific authorization of the patient or, if the patient is deceased or otherwise unable to consent, the specific authorization of the patient’s legally authorized representative.
- 5.0 If a case report involving three or fewer patients containing PHI will be submitted for publication, this activity is not part of standard health care operations and requires the specific authorization of the patient or, if the patient is deceased or otherwise unable to

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