

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

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Institutional Review Board

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DHHS FWA #00003630

IORG #0000043

IRB 1 Registration #00000061

IRB 2 Registration #00005033

Single Case Report and Limited Case Series

A single case report or a limited case series involving data from two or three patients does not meet the definition of “research” and does not require IRB review. [45 CFR 46.102\(d\)](#) defines research as “...a systematic investigation...designed to develop or contribute to generalizable knowledge...” The HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB.

A case series involving data from more than 3 patients meets the definition of research and requires IRB review.

NOTE: Case reports for publication must be prepared in accord with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be done with authorization of the patient, or, meet one of the four HIPAA exceptions. Please contact The Office of Integrity and Compliance prior to submission of the case report to assure HIPAA compliance.