

MEMO

TO: MHRI Research Community
FROM: Rebecca Ballard, Director Office of Research Integrity
CC: Neil Weissman, MD, President, MedStar Health Research Institute and Institutional Official
DATE: August 1, 2017
RE: Case Reports as Not Human Subjects Research

Activities meeting the DHHS definition of research and involves human subjects are subject to IRB review and approval.

In medicine, a **case report** is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient.

MedStar Health Institutional Review Board has determined that a case report of less than three (3) patients **does not meet the DHHS definition of research** (45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(1)(1/19/2017)) **or the FDA definition of clinical investigation** (21 CFR 46.102(c)) and therefore are not subject to IRB review requirements and **do not require IRB approval**.

Case reports for publication may be considered a disclosure of protected health information (PHI) and therefore must be prepared in accordance with HIPAA. Please review the [attached guidance](#) to determine if a patient's authorization is required.

Please review the Frequently Asked Questions on Case Reports found [here](#). Questions related to this determination can be directed to MHRI ORI at 301-560-2912.

Questions related to HIPAA requirements should be directed to researchcompliance@medstar.net or the corporate Privacy Director at privacyofficer@medstar.net.