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**301-560-2912**

**medstarresearch.org**

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: July 1, 2025

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 up to (3) patients [3 or fewer] **does not meet the DHHS definition of research** (45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(l)(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 guidance document included on the IRB website along with this memo to determine if a patient’s authorization is required.

Please review the Frequently Asked Questions on Case Reports found also on the IRB website along with this document. 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.