Albert Einstein College of Medicine

Case Report Guidelines

I. Purpose

The purpose of these guidelines is to help investigators determine when case reports require Einstein Institutional Review Board ("IRB") review and/or permission from the subject.

II. Scope

These guidelines apply to investigators affiliated with Albert Einstein College of Medicine ("Einstein") and Montefiore Medical Center ("MMC").

III. Definitions

Case Report: Case reports describe (a) the course of medical treatment involving one or more patients and having a unique outcome, or (b) the handling of a unique clinical case. Treatment and/or case management will have been accomplished without any research intention (i.e., there was no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s)).

Research (as defined by the Department of Health and Human Services): Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

IV. Guidelines

Case Reports Involving Three or Fewer Patients

Case reports involving three or fewer cases do not meet the Department of Health and Human Services definition of "research" and do not require submission to the Einstein IRB for review.

Consent Requirements for Case Reports Involving Three or Fewer Patients

Although a case report may not require IRB review, consent is generally required from the patient in order to publish the case report. HIPAA Privacy Rule provisions may apply, and therefore the information presented in the case report must be fully de-identified as required under HIPAA (i.e., there can be no reference to name; address; all elements of dates (except year) for dates directly related to an individual; telephone or facsimile numbers; email address; social security number; medical record number; health plan beneficiary numbers; hospital account numbers; certificate/license numbers; vehicle identifiers; device identifiers; web URLs; IP addresses; biometric identifiers; full-face photo images or comparable images; any other unique identifying number, characteristic or code).

It may not be possible to fully de-identify the individual described in a case report, even if all HIPAA identifiers are deleted since the unique character of the patient's experience can serve as an identifier in its own right. Moreover, items such as the patient's age and gender, in combination with diagnosis and course of treatment, the name of the treating physician who authored the case report, the name of the institution, and the date of publication may cause others to be able to identify the patient. The individual patient (or appropriate surrogate) should sign a HIPAA Authorization authorizing the use of the description of their individual case situation. Signed authorization must always be obtained if a potentially identifiable image of the subject is to be included in the report. The case report authorization form is available on the Office of Human Research Affairs website, which may be used to comply with institutional policy.

If you are unable to obtain consent from the patient, contact the MMC Privacy Officer (privacyofficer@montefiore.org) for further guidance.

Case Reports Involving more than Three Patients

Case reports involving more than three subjects (i.e., a case series) meet the definition of "research," and review by the Einstein IRB is required. The Einstein IRB's informed consent policies and procedures for human research apply.

V. Effective Date

Effective as of: March 10, 2020

Revised as of: August 1, 2023

VI. Document Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this document. Einstein's Executive Dean is the Responsible Executive for this document. The OHRA Director is the Responsible Officer for the management of this document.