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.

Although a case report may not require IRB review, HIPAA Privacy Rule provisions may apply and ethical concerns can arise if identifiable information is published. Therefore, the case report authorization form is available on the OHRA website, which may be used to comply with institutional policy.

If you are unable to obtain authorization 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

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.