

# Protocol Exception Request Procedure

## I. Purpose

This Procedure describes the process for submitting a request for a one-time deviation from an already-approved protocol, or for submitting a request to continue research interventions during a lapse of Institutional Review Board (“IRB”) approval.

## II. Scope

This Procedure applies to all human research conducted under the purview of the Einstein IRB.

## III. Definitions

**Protocol Exception:** A planned, one-time deviation from the IRB-approved protocol (e.g. enrollment of a subject who does not meet inclusion criteria, or a one-time dose change for a single subject).

## IV. Procedure

1. Requests for one-time deviation from the approved protocol must be submitted to and approved by the IRB prior to implementation.
  - 1.1. Such requests will be reviewed by the Executive Chair to determine whether the change has the potential to increase the risk, reduce the benefit, or require a different informed consent form or process.
2. Requests to continue research interventions or interactions with currently enrolled subjects during lapse of IRB approval may also be submitted as a protocol exception request.
  - 2.1. Such requests will be reviewed by the Executive Chair to determine whether the continuation of research interventions is in the best interest of already enrolled subjects.

## V. Effective Date

Effective as of: 17 December 2019

## VI. Procedure Management and Responsibilities

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