

Treatment Use of Investigational Devices

I. Purpose

This Procedure outlines requirements for treatment use of investigational devices at sites under the auspices of the Einstein Institutional Review Board (“IRB”).

II. Scope

The following Procedure covers all treatment use of investigational devices at sites under the auspices of the Einstein IRB.

III. Definitions

Treatment Use: The use of non-FDA approved, investigational drugs or devices for clinical care through the FDA’s Expanded Access Program.

IV. Procedure

Treatment use of investigational devices requires prior IRB review (with the exception of Emergency Use).

A. Compassionate Use

FDA recognizes that there are circumstances in which an investigational device is the only option available for a patient faced with a serious or life-threatening disease or condition.

The compassionate use provision provides a path to accessing investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. Compassionate use can be for devices that are being studied in a clinical trial under an IDE for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. It can also be used for devices that are not being studied in a clinical investigation (i.e., an IDE for the device does not exist). This provision is typically approved for individual patients but may be approved to treat a small group, if the small group request is under an IDE.

Criteria:

- The patient has a life-threatening or serious disease or condition; and
- No generally acceptable alternative treatment for the condition exists.

Prior FDA approval and concurrence by an IRB chair is needed before compassionate use occurs.

Before using the device, the PI or treating physician must submit the following information to the IRB: an IRB application with a brief description of patient(s) situation, treatment and monitoring plan; documentation of FDA approval for compassionate use of the device; independent assessment from uninvolved physician, if available; and a copy of the informed consent form.

Any problems that occur as a result of device use should be reported to the IRB within 5 business days.

B. Treatment IDE

An approved IDE specifies the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in the study. During the course of the clinical trial, if the data suggest that the device is effective, then the trial may be expanded to include additional patients with life-threatening or serious diseases. This is called treatment use, and is subject to treatment investigational device exemption (IDE) regulations.

Criteria for treatment use of an investigational device:

- The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;
- There is no comparable or satisfactory alternative device available to treat or diagnose the disease or condition in the intended patient population;
- The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or all clinical trials have been completed; and
- The sponsor of the controlled clinical trial is pursuing marketing approval/clearance of the investigational device with due diligence.

An "immediately life-threatening" disease means a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. "Treatment use" of a device includes the use of a device for diagnostic purposes.

Review by a convened IRB is required for treatment use of medical devices under a treatment IDE. The IRB requires written communication from the FDA documenting the treatment IDE number in order to approve the treatment use protocol. Other documentation of the treatment IDE may be accepted at the discretion of the Director or his or her designee.

V. Effective Date

Effective as of: July 1, 2020

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.