Albert Einstein College of Medicine

# Investigational Drug Procedure

## I. Purpose

This Procedure outlines requirements for research involving investigational drugs or biologics at Albert Einstein College of Medicine ("Einstein" or "College of Medicine").

## II. Scope

The following Procedure covers all research involving the use of investigational drugs or biologics under the auspices of the Einstein IRB.

## III. Definitions

**Clinical Investigation:** Any experiment that involves a test article and one or more human subjects. An "experiment" is any use of a drug except for the use of a marketed drug in the course of medical practice.

**Drug:** A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part, or accessory of device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process).

**Investigational Drugs or Biologics:** A drug or biologic that is used in clinical investigation. Such drugs or biologics might be either commercially available or not commercially available and used according to, or outside of, the FDA-approved indications.

**Investigational New Drug (IND):** Any drug or biological product for which the FDA issues an Investigational New Drug (IND) number to allow the drug to be used in a clinical investigation.

## IV. Procedure

Use of investigational drugs must be conducted according to FDA IND regulations (21 CFR 312) and other applicable FDA regulations. When research involves the use of drugs or biologics other than the use of an FDA approved, marketed drug or biologic in the course of medical practice, the IRB will confirm and document that either:

**A. The drug or biologic has a valid IND Application**

Documentation of the IND is required for approval of studies involving investigational drugs or biologics. To document the IND, the IRB requires written communication from the FDA. Investigator's brochures may not be used to validate an IND. Other documentation may be accepted at the discretion of the OHRA Director.

The IND goes into effect 30 days after the FDA receives the IND, unless the sponsor receives earlier notice from the FDA.

**B. The protocol meets IND Exemption**

An IND exemption applies to the investigation of a drug product that meets all of the following conditions:

1. The drug product is lawfully marketed in the United States.
2. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.
3. In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug.
4. The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product.
5. The investigation is conducted in compliance with 21 CFR 50 and 56.
6. The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

Note: The following are also exempt from the IND requirements: (a) a clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND; (b) a drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160; and (c) substances either recognized as GRAS (generally recognized as safe) common to the food supply or used in topical applications, or substances that are naturally occurring in the human body such as metabolites. These metabolites may be isotopically labeled either with naturally occurring non-radioactive or radioactive isotopes. Appropriate QC and sterility data must be provided to the IRB for parenteral use. For radioactive metabolites, radiation exposure calculations must pass review by Radiation Safety and be available to the full board prior to final IRB review.

For clinical investigations involving an in vitro diagnostic biological product, an IND is not necessary if: 1. It involves one or more of the following: (a) Blood grouping serum, (b) Reagent red blood cells or (c) Anti-human globulin; 2. It is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and 3. It is shipped in compliance with 312.160.

As part of the protocol review, the IRB will determine the appropriateness of the exemption.

## V. Effective Date

Effective as of: 22 August 2019

Revised as of: 30 August 2023

## 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.