
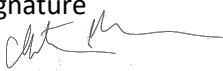


Standard Operating Procedures		
SOP 308.2 Revision 2	TITLE: Review of FDA Regulated Drugs and Devices	Effective Date: 5/26/2021
Approved By: OIRB Director	Signature 	Date 5/28/21
Approved By: IRB Chair	Signature 	Date 5/28/21

PURPOSE

To define policies and procedures for IRB review of investigational drugs and devices

REVISIONS FROM PREVIOUS VERSION

Added definitions for clinical investigations and IND exemptions

POLICY

The UNM IRB does not review projects involving FDA regulated investigational drugs (i.e. does not meet Investigational New Drug (IND) Exemption requirements) or significant risk devices. UNM relies on qualified, accredited external IRBs to provide review and oversight of these projects. The IRB conducts initial and continuing review of projects involving non-investigational drugs and devices that are exempt from Investigational Device Exemption (IDE) requirements or are nonsignificant risk devices according to relevant SOPs. Additional regulatory determinations are made as required and described below. UNM IRB has published guidance to assist investigators in understanding their responsibilities under FDA regulations.

DEFINITIONS

Clinical investigation: any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Device: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes 21 U.S.C. 321(h).

Drug: (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

IDE Exempt Investigations: All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from 21 CFR 812 are described in §812.2(c) of the IDE regulations. Studies exempt from the IDE regulations include:

1. a legally marketed device when used in accordance with its labeling
2. a diagnostic device if it complies with the labeling requirements in §809.10(c) and if the testing:
 - a. is noninvasive;
 - b. does not require an invasive sampling procedure that presents significant risk;
 - c. does not by design or intention introduce energy into a subject; and
 - d. is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure;Additional guidance for an in vitro diagnostic device studies can be found in "Regulating In Vitro Diagnostic Device (IVD) Studies."
3. consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
4. a device intended solely for veterinary use;
5. a device shipped solely for research with laboratory animals and contains the labeling "CAUTION – Device for investigational use in laboratory animals or other tests that do not involve human subjects."

IND Exemptions: The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements to obtain an IND Application if all the following apply:

- (i) The drug is lawfully marketed (FDA approved) in the U.S.;
- (ii) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- (iii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- (iv) The project does not involve a route of administration or dosage level or use in a clinical population or other factor that significantly increases the risk associated with the use of the drug;
- (v) The drug is not represented in a promotional context as safe or effective for the purposes under investigation.

Investigator: an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team (21 CFR 50.3(c)).

Nonsignificant Risk (NSR) Device: a device that does not meet the definition for a significant risk device as described below.

Significant Risk Device: Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Sponsor: a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators (21 CFR 50.3(d)).

Sponsor-investigator: an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency (21 CFR 50.3(e)).

RESPONSIBILITIES

Execution of SOP: OIRB Staff, IRB, Researchers.

PROCEDURE

Review of Projects Involving IDE Exempt or NSR Devices

1. During pre-review, OIRB staff will either confirm the validity of the Investigational Device Exemption (IDE) from the FDA or verify that a Device Information Form has been submitted that includes a justification for being IDE exempt or a NSR determination.
2. Initial review of projects involving investigational devices will be conducted according to SOP 303 Initial Full Review. Continuing review will be conducted not less than once per year and according to SOP 305 Continuing Review.
3. The IRB will ensure any NSR investigational device is labeled as such and does not bear any statement that is false or misleading and does not represent the device is safe or effective for the purposes for which it is being investigated.
4. Unanticipated adverse device effects will be reported to the IRB according to SOP 401 Reporting and Review of Events Involving Risk to Participants or Others.

Review of Projects Involving FDA Approved Drugs

1. During pre-review, OIRB staff will verify that a Drug Information Form has been submitted.
2. If the project involves an investigational drug that requires an IND, the project will be deferred to an external IRB.
3. Initial review of projects involving FDA approved drugs will be conducted according to SOP 303 Initial Full Review or SOP 304 Expedited Review of Federally Funded Research, depending on the risk

level of the project and applicability of expedited review procedures. Continuing review will be conducted according to SOP 305.

4. The IRB will confirm and document that:
 - a. The project is neither intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used in support of any other significant change in labeling for the drug;
 - b. The project is not intended to support a significant change in the advertising for the product;
 - c. The project does not involve a route of administration or dosage level or use in a clinical population or other factor that significantly increases the risk associated with the use of the drug;
 - d. The drug is not represented in a promotional context as safe or effective for the purposes under investigation.

REFERENCES

21 U.S.C. 321
21 CFR 50
21 CFR 56.109(f)
21 CFR 312
21 CFR 812