OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP 308.0 Revision 0	**TITLE: Review of FDA Regulated Drugs and Devices**	Effective Date: 1/30/2019
Approved By: OIRB Director	Signature	Date 2/5/2019
Approved By: IRB Chair	Signature	Date 2/5/2019

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

REVISIONS FROM PREVIOUS VERSION
None

POLICY
The UNM IRB does not review projects involving FDA regulated investigational drugs (i.e. does not meet IND Exemptions 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 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
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).

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 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 including a justification for 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 the 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. 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.

3. 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 the 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