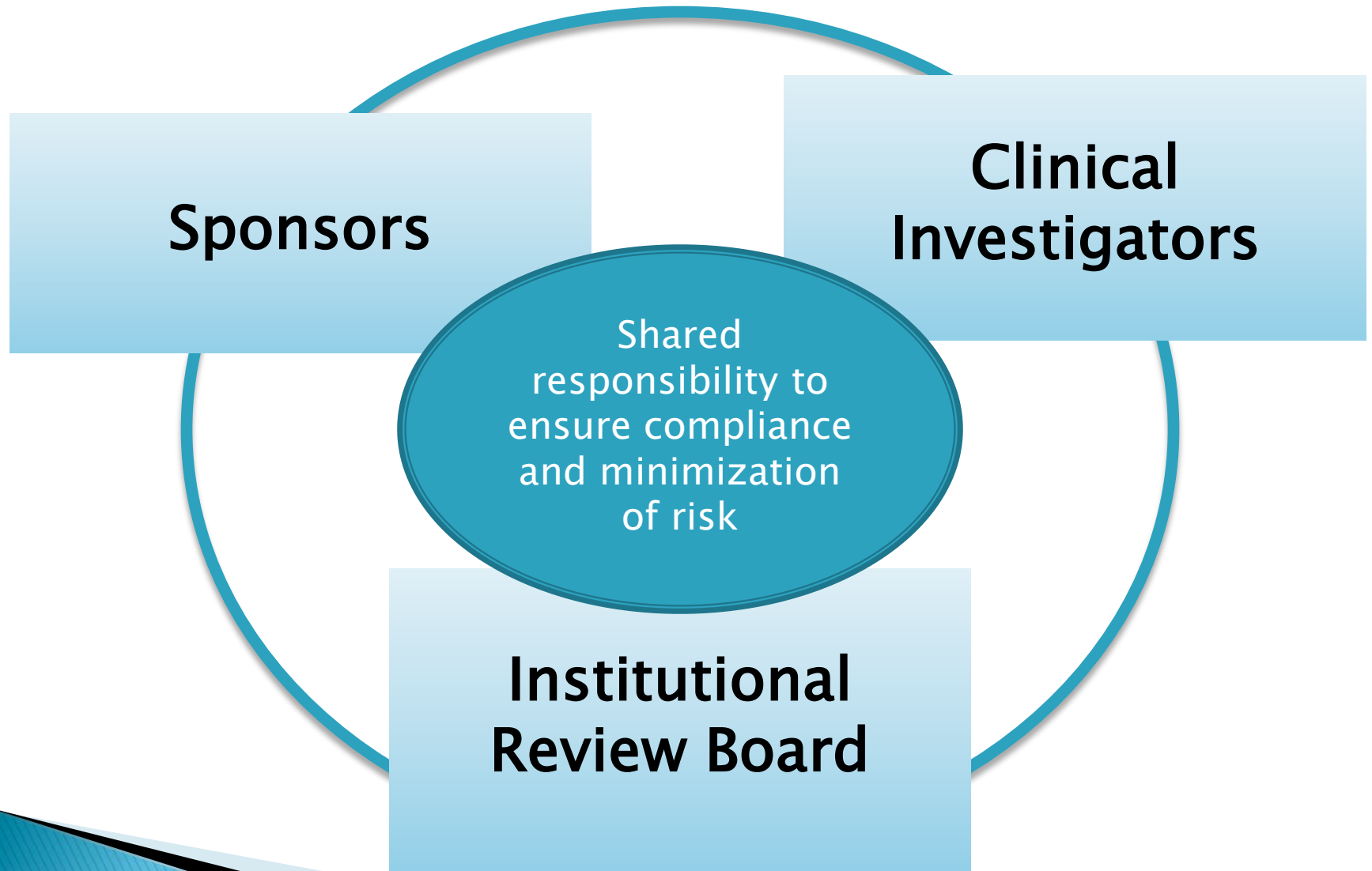


# IRB Responsibility in IND/IDE Review

# Oversight Responsibilities



## Medical Device

- ▶ Does not achieve purpose by chemical action or metabolization
  - Substantial equivalence
  - 510K
  - Immediate marketing
- ▶ No FDA determinations  
IRB evaluates device like any other study procedure

## Investigational Device

- ▶ Undergoing studies to evaluate the safety and / or effectiveness of the device
  - Comply with 21 CFR 812
- ▶ IRB determines significant or non-significant risk

# Significant Risk Device Study

- ▶ A study of a device that presents potential for the serious risk to the health, safety or welfare of a subject and
  - Is an implant
  - Used to support or sustain human life
  - Is of substantial importance to **diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, *OR***
  - Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject

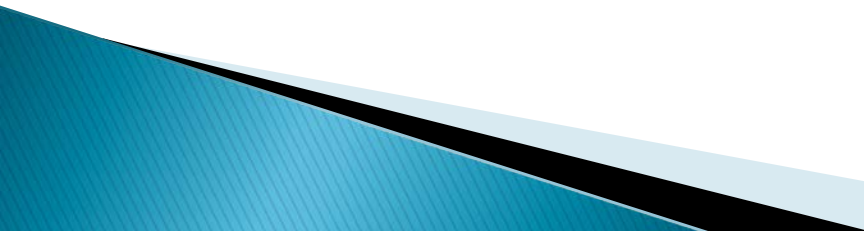
*Must be conducted with the prospective approval of an IDE application by the FDA*

# Non-Significant Risk Device Study

- ▶ Does not meet the definition of a Significant Risk Device Study
  - Daily wear contact lenses
  - MRI (within parameters)
  - Menstrual pads and tampons
  - Wound dressings
  - Ultrasound (within parameters)

*No application to the FDA. Follow abbreviated IDE requirements (21 CFR 812.2(b)) IRB serves as surrogate for review, approval and continuing review*

# Making a Determination

- ▶ Decisions based on the nature of the device and the proposed use of the device in the study
  - ▶ Initial determination by Sponsor–Investigator
  - ▶ IRB reviews justification
    - Non–Significant Risk: IRB can grant approval for investigator to begin
    - Significant Risk: Application to the FDA under 21 CFR 812 for an IDE
- 

2.2.1 Does this research study involve an evaluation of the safety and/or effectiveness of one or more devices not currently approved by the FDA for general marketing?

\* No

2.2.2 Does this research study involve the use or evaluation of the safety and/or effectiveness of one or more devices approved by the FDA for general marketing?

\* Yes

2.2.2.1 Does this research study involve an evaluation of one or more FDA-approved devices for a clinical indication, subject population, and/or operational parameter that is not specified in the current FDA-approved product labeling for that device (i.e., for an "off-label" indication)?

\* Yes

2.2.2.1.1 List each of the devices being evaluated for an "off-label" indication. Specify for each listed device the corresponding Investigational Device Exemption (IDE) number for this device/research study; or provide a justification for why you feel that this device and its "off-label" use, as proposed in this research study (i.e., to include potential failure of the device) constitute a non-significant risk to the involved research subjects.

\*

Device	IDE #	Non-significant risk justification
<a href="#">View</a> Infinion 16 Spinal Cord Stimulator from Boston Scientific		The off-label approach used in this study is nearly identical to the FDA-cleared procedure (PMA P030017) in which these devices are placed in the epidural space for treatment of chronic intractable pain of the trunk and/or limbs. As in that procedure, the device will be tunneled percutaneously through the skin and secured in place with tape, maintained for multiple days, and removed by gently pulling on the leads. The devices will be placed during a fluoroscopically guided outpatient procedure, which typically takes 1-2 hours) and kept under the skin for less than 30 days. Removal will be accomplished during an outpatient clinic visit. We will target a slightly different anatomical target (the dorsal spinal nerves, rather than the dorsal columns), by using the stylet included with the device to steer it laterally in the epidural space. The proposed study is a physiological experiment to characterize the types of sensations that can be evoked by stimulation of the dorsal spinal roots, and is not intended to evaluate the safety of the spinal cord stimulator system. As such, we believe that this is a non-significant risk study because 1) devices will be placed for less than 30 days, 2) the system will not be used to support or sustain life, 3) the system will not be used to diagnose or treat disease, and 4) based on the rates and types of complications that occur with the use of these devices, it does not present a serious risk to the health, safety, or welfare of subjects.

# Unapproved Drugs in Research

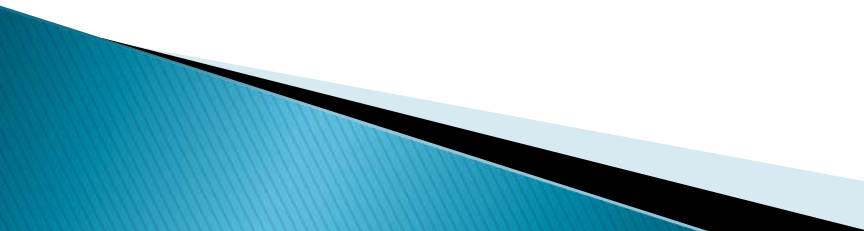
## IND Required.

21 CFR 312: Investigational New Drug Application

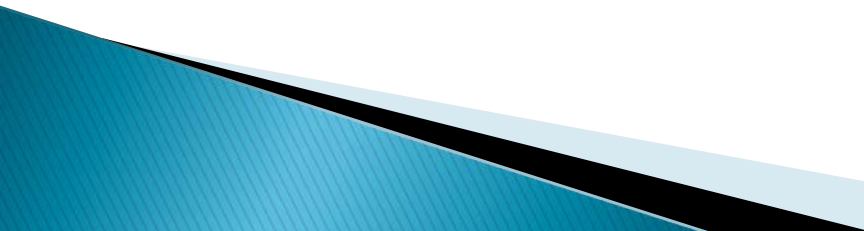




# Off-Label Drug Use in Research

1. a systematic investigation to evaluate the safety and effectiveness of the drug;
  2. the collection of data with the intent to report such in a scientific publication;
  3. any consideration other than the direct welfare of the patient (e.g., a selection between the drug or placebo, or between two or more equivalent drugs, based on randomization; the administration of the drug to a normal “control” subject); or
  4. a use not based on firm scientific rationale and/or medical evidence.
- 

# IND Not Required

1. it is not intended to be reported to the FDA in support of a new indication for use or to support any other significant change in the labeling of the product;
  2. it is not intended to support a significant change in the advertising for the product;
  3. it does not involve a route of administration of dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of risks) associated with the use of the project; and
  4. it is conducted in compliance with the requirements for IRB review and informed consent.
- 

2.1.3 Does this research involve the use or an evaluation of the effectiveness and/or safety of one or more drugs or biologicals currently approved by the FDA for general marketing?

\* yes

2.1.3.1 Are the FDA-approved drugs or biologicals being evaluated in this research study for a new clinical indication, different population, or route of administration and/or dosage level that is not currently specified in the FDA-approved product labeling?

\*yes

2.1.3.1.1 By using the "Add" button available below, list and specify the following for each of the FDA-approved drugs or biologicals being evaluated under this research study.

- Whether data from this research will be reported to the FDA in support of a new indication for the use of this drug product or to support any other significant change in the labeling (i.e., new indication). If **Yes**, provide the corresponding IND number.
- Whether data from this research will be used to support a significant change in the advertising for this drug product (i.e., new advertisement). If **Yes**, provide the corresponding IND number.
- Whether the proposed 'off-label' evaluation of the approved drug is felt to significantly increase the risks (or decrease the acceptability of risk) compared to the current approved uses of this drug or biological. If **Yes**, provide the corresponding IND number. If **No**, provide a justification for why the risk is not increased or the acceptability of risk is not decreased (i.e., risk justification).

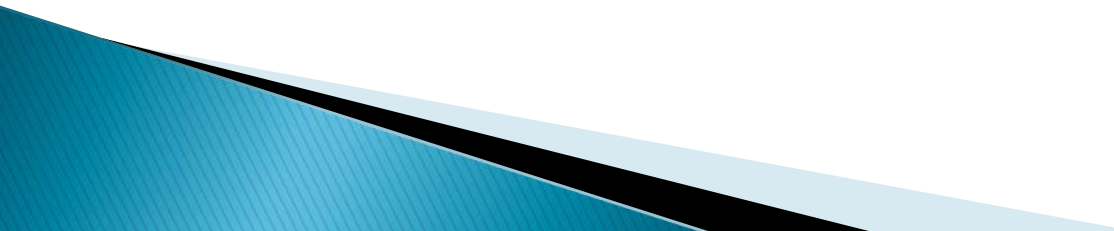
Approved Drug/Biologic	New Indication	New Advertisement	Risk Concern	Risk Justification/No IND	IND #
<a href="#">View</a> Minocycline	no	no	No	Minocycline, currently approved by FDA for acne vulgaris, some sexually transmitted diseases and rheumatoid arthritis, has near 100% bioavailability, has rare severe adverse side effects after long-term administration and due to its high lipophilia, passes easily the BBB 30 enabling its use in the treatment of diseases of CNS. Minocycline has been found safe for long-term use in the doses of 200mg/day. Minocycline was used for up to 2 years in patients with intracranial arterio-venous malformations (AVMs) and aneurysms. Similarly Minocycline was tested in patients with Parkinson's symptoms using daily doses of 200mg for up to two years.	

**Upload information on FDA approved indications/doses and FDA exemption letter if applicable:**

Name	Modified Date
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There are no items to display

# Additional Considerations

- ▶ The IRB assesses training, experience and qualifications of the investigators in context of the study
  - ▶ The IRB assesses the adequacy of the site where the research procedures are being conducted
- 

# Questions?

Specialized education  
available upon request:

[askirb@pitt.edu](mailto:askirb@pitt.edu)