IRB APPLICATION OF FDA REGULATIONS

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Acknowledgement Ada Sue Selwitz
FDA IRB Review & Informed Consent Regulations apply to Clinical Investigations with FDA Regulated Products
Some Clinical Investigations are also subject to FDA Investigational New Drug (IND) or Investigational Device Exemption (IDE) Regulations.
The Sponsor or Sponsor-Investigator is responsible for complying with IND or IDE requirements which may involve submitting an IND or IDE application to FDA.
FDA requires an IRB to:
- evaluate investigator qualifications;
- assess adequacy of facilities; and
- question the need for an IND or IDE.
IRB interactive flowchart for identifying and applying FDA regulations to studies involving devices.

Click Question Icon to link to FDA Guidance
Medical Device
- Investigational device not approved or cleared by FDA
- New use of a marketed device
- Component, part, accessory, battery
- In-vitro device, assay or reagent
- Software or computer applications (e.g. MRI)
- Select Mobile Medical Application
- A homemade device

Clinical Investigation
Experiment in one or more human subjects; designed to evaluate the safety or effectiveness of a medical device in subjects, controls or specimens.

21 CFR 56.102

Section 201(h) of the FD&C A
Is study IDE Exempt?

Yes, study meets exemption criteria 21 CFR 812.2c

Ensure consent includes reference to FDA. If no greater than minimal risk, study may qualify for Expedited IRB Review Category 1

Submit for Full IRB Review with sponsor’s SR/NSR determination

Examples of IDE Exempt Trials

*(must meet all applicable conditions)*

- Study of device used in accord with FDA approved labeling and indications* and no intent to report to FDA in support of new indication or label change.
- An in-vitro diagnostic device IF 4 criteria are met.
- Low risk studies that DO NOT collect data on safety or effectiveness (e.g., consumer preference, cosmetic modification).
- Device intended solely for veterinary or research animals.

* Provide IRB with manufacturing information, labeling, instructions, warnings, or other material describing approved indications.
**Significant Risk (SR)**

Presents a potential for serious risk to the health, safety, or welfare of a subject, or an implant, or designed to support or sustain human life, or substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health.

**NON Significant Risk (SR)**

Does NOT meet any criteria in significant risk definition. Involves a level of risk that doesn't warrant review by FDA; IRB acts as surrogate for FDA.
IRB interactive flowchart for identifying and applying FDA regulations to studies involving drugs or biologics.
**Drug/Biologic**
- Investigational drug not approved by FDA
- New indication for approved drug
- Other compounds intended to affect structure or function of the body (e.g., cosmetic)
- Dietary supplements, botanicals, probiotics, etc. if testing ability to diagnose, mitigate, treat or prevent disease.
- Vaccine, blood product, In-Vitro Assay, other biologics
- Electronic Cigarettes used to treat/prevent addition
  
  [www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm)

**Clinical Investigation**
- Experiment in one or more human subjects; use of a drug in a study, other than the use of an approved drug in the course of medical practice.
  - [21 CFR 56.102](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm)
Is study IND Exempt?

- Yes, study meets exemption criteria
- 21 CFR 312.2c
- Ensure consent includes reference to FDA.
- If no greater than minimal risk, study may qualify for Expedited IRB Review Category 1

- No
- Unsure

- Yes, study meets exemption criteria
- 21 CFR 312.2c
- Ensure consent includes reference to FDA.
- If no greater than minimal risk, study may qualify for Expedited IRB Review Category 1

- No
- Unsure

- Sponsor contacts FDA for an IND determination
- Submit FDA Correspondence
- Submit FDA IND documentation

IRB Review

Examples of IND Exempt Trials

**Unapproved use of an approved drug** if all criteria met:
- Lawfully marketed in US;
- No intent to report to FDA to support new indication;
- No intent to support change in labeling or advertising;
- Does not involve route of administration, dose, population that significantly increases risk or decreases tolerability;
- Conducted in compliance with FDA IRB review and informed consent regulations; and
- study is not intended to promote drug product.

**Dietary Supplement** if study designed to:
- only to reduce risk of a disease;
- evaluate effect on structure or function of the body; or
- support a new or expanded health claim, **and**
- conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.