THE UNIVERSITY OF ARIZONA Research & Partnerships

Investigational Device Exemptions (IDE)

What is a medical device?

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis, curing, mitigation, treatment, or prevention of disease or other conditions in man or intended to affect the structure or any function of the body of man, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

When do U.S. Food & Drug Administration (FDA) regulations <u>not</u> apply?

1) Using an FDA approved device to test a physiologic principle where no data is collected about the device.
2) Using an FDA approved device to address a research question, and no data is collected about the device. For example, if an investigator needs to note the subject's weight using a scale (which is a device), but they are not interested in researching the scale itself, then it's not an FDA regulated study.
3) Using a device for normal clinical purposes.

When do FDA and Institutional Review Board (IRB) regulations apply?

These regulations apply when the purpose of the study is to evaluate the safety or effectiveness of a medical device in human subjects or even human specimens (e.g., in vitro diagnostic devices). The IRB must document the device has been issued an Investigational Device Exemption (IDE) by the FDA, the device fulfills the requirement for an abbreviated IDE, the device is not a banned device, and the sponsor labels the device according to 21 CFR 812.5:

- The sponsor obtains IRB approval of the investigation after presenting the IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;
- The sponsor ensures that each investigator participating in an investigation of the device obtain from each subject under the investigator's care consent under 21 CFR 50 and documents it, unless documentation is waived;
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

If a study involves a medical device under these circumstances, submit the *Appendix for Devices* in eIRB along with the device manual, FDA documentation of approval or IDE, and any additional information the IRB may need to make their determinations regarding significant or non-significant risk determinations related to the device itself.

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When is an Investigational Device Exemption (IDE) required?

An IDE may be required for studies designed to:

- Supporting marketing applications;
- Collect safety and effectiveness information; or
- Sponsored studies of an unapproved device or a new intended use of an approved device, even if a marketing application is not planned.

An IDE allows for the medical device to be used in a clinical study to collect the safety and efficacy data required to support a marketing application. "Exempt" means the device is exempt from the laws that prohibit unapproved products to move in interstate commerce. A device may be IDE exempt if:

- A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
- A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
    - Is Non-invasive,
    - Does not require an invasive sampling procedure that presents significant risk,
    - Does not by design or intention introduce energy into a subject, and
    - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.

Holder of the IDE

If the University of Arizona is the holder of the IDE, there is a potential institutional conflict of interest. An outside IRB may need to review the protocol to avoid any potential conflicts. Contact the Office for Responsible Outside Interests for more information: COI@arizona.edu or 520-626-6404.

What are the different regulations for device studies?

If a project involves an FDA-regulated medical device, it must fit into one of the following categories:

1. **Studies Exempt from IDE Requirements:**

a. Those using a device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
b. Those using a device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
c. Those involving a marketed medical device in which the device is being used or investigated within the approved indications.
d. Those that are consumer preference testing, testing of a device modification or testing of a combination of two or more devices in commercial distribution if the testing does NOT collect safety or effectiveness data, or put subjects at additional risk.
e. Those using a diagnostic device study under the following circumstances:
    i. Complies with the requirements at 21 CFR 809.10(c) for labeling
    ii. Is Non-invasive,
    iii. Does not require an invasive sampling procedure that presents significant risk,
    iv. Does not by design or intention introduce energy into a subject, and
    v. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
f. Those submitted with correspondence from the FDA indicating that the device is NSR or that the study is exempt from IDE requirements.

2. Significant Risk (SR) Device Research

a. Significant risk device is an investigational device that:
    1) is intended as an implant and presents potential for serious risk to the health, safety, or welfare of a subject;
    2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;
    3) 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
    4) otherwise presents a potential for serious risk to a subject.
b. The study is being conducted under a valid FDA approved IDE.

3. Non-Significant Risk (NSR)

a. A study using a device that has been deemed non-significant risk either by the FDA, IRB, or sponsor is considered to have an approved Abbreviated IDE. An Abbreviated IDE has regulatory requirements including labeling, informed consent, monitoring, records, reports, and prohibition on promotion. Reports are only submitted to the IRB. Please refer to Human Subjects Protection Program (HSPP) Guidance, *Abbreviated IDE Requirements* for more information.
b. Unless the FDA has made the SR or NSR determination, a convened IRB must make this determination.

c. If the IRB disagrees with the sponsor's NSR assessment and decides the study is SR, the IRB must tell the clinical investigator, and where appropriate, the sponsor (21 CFR 812.66). SR device studies must have an IDE application approved by FDA before they may proceed. The Principal Investigator follows full regulatory requirements under the purview of both the FDA and the IRB.

What about device classifications?

The FDA may classify a device as class I, II or III. The higher the class, the more risk that device holds. This classification is based on level of control to assure the safety and effectiveness of the device for marketing- not for research.

Which regulatory device categories may be eligible for Expedited review?

For a device study to be eligible for Expedited review, the device must:

- Present no more than minimal risk to the subject; and
- Meet one of the criteria in Expedite Category 1b: Research on medical devices for which:
  (i) an IDE application (21 CFR Part 812) is not required; or
  (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Resources:

- HSPP IDE Resources: https://research.arizona.edu/compliance/human-subjects-protection-program/resources-investigators/investigational-device