

# Use of an Investigational Device in Human Subjects Research Procedure

## Scope

Applies to Mayo Clinic Human Research Protection Program when involved in Human Subjects Research for which the Mayo Clinic Institutional Review Board (IRB) is the IRB of Record.

## Purpose

To direct and inform Investigators, IRB Committee members and IRB staff of the requirements for human subject research when using Food and Drug Administration (FDA) regulated investigational devices.

## Equipment/Supplies

N/A

## Procedure

### IRB Responsibilities

1. Ensure that Investigators comply with all applicable regulations pertaining to investigational devices and that all proposed uses are reviewed and approved by the IRB as defined by Federal regulations.
2. Review the initial research project application. Initial project applications, modifications and continuing review reports are reviewed using the criteria described in this document and in the documents [IRB Initial Approval of Research](#), [Modifications to Previously Approved or Exempt Research](#) and [Continuing Review of Research](#).

### Investigator Responsibilities and Determination of Risk

1. Request IRB approval for the use of an investigational device in a research project and submit an IRB electronic (IRBe) application. In the IRBe application, provide (or provide documentation of) the following information:
  - a. Level of risk: Significant Risk or Non-Significant Risk (NSR) as determined by the sponsor when the device is used as described in the research project proposal.
    - i. Inform the IRB if other IRBs have reviewed the proposed study and what risk determination was made
    - ii. IRB must be informed of the FDA's assessment of the device's risk, if such an assessment has been made
  - b. Correspondence from the Sponsor and/or FDA supporting the determination that the proposed use of the device is NSR or the Investigational Device Exemption (IDE) approval letter or conditional approval letter from the FDA for Significant Risk devices.
  - c. IDE number (for Significant Risk devices)
  - d. A description of the device
  - e. Reports of prior investigations with the device

- f. The investigational plan/protocol/research project proposal
  - g. A description of subject selection criteria
  - h. A description of planned monitoring procedures
  - i. Proposed consent form(s)
  - j. IDE exemption criteria, if applicable
  - k. Any other information that the IRB requires in order to conduct its review and make a determination
2. Notify the Sponsor of the IRB's risk determination.
  3. Ensure the research project is conducted according to the IRB approved research project proposal and in compliance with the requirements of this document and other applicable requirements and regulations.
  4. Ensure protection of the rights, safety, and welfare of the subjects.
  5. The Investigator must promptly report all Unanticipated Problems Involving Risk to Human Subjects or Others (UPIRTSO) or any serious or continuing noncompliance to the IRB. Refer to [Submitting a Reportable Event to the IRB Policy](#).
  6. Responsible for controlling the investigational device.
  7. Do not make changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
  8. Comply with IRB and regulatory requirements for IRB review and approval of the initial, modification, and continuing review report submissions.

## Convened IRB Responsibilities

1. Review the application and make a determination of risk based on the proposed use of the device as proposed in the study under review, *not on the device alone*. The IRB may consult with the FDA for its opinion.
  - a. If an NSR determination is made by the IRB, the IRB will continue its review to determine whether the research proposal meets the criteria for IRB approval. If the NSR device study receives IRB approval, the Investigator and sponsor are expected to comply with [21 CFR 812.2\(b\)](#), the abbreviated FDA requirements for IDEs (see below).
  - b. If there is disagreement between IRB and the sponsor's **Non-Significant Risk** assessment and a determination is made that the proposed use of the device presents **Significant Risk**, inform the Investigator, and where appropriate, the sponsor. In this case, the IRB will review the research project again only after the sponsor has obtained an IDE and the IDE approval letter or conditional approval letter from the FDA has been submitted to the IRB.
  - c. If the FDA does not approve an IDE, study of the device will not be allowed.
  - d. If the **FDA** rules that the research project is **Significant Risk** after the sponsor and the IRB have determined that the research project is NSR and the research project has been initiated, suspend the currently approved study detailing criteria for suspension.

- e. The research project may not reopen until an IDE is approved by the FDA and the approval letter or conditional approval letter from the FDA is submitted to the IRB for review by a Convened IRB.

## **Abbreviated Investigational Device Exemption Requirements**

The FDA considers an investigation of an NSR device to have an approved Investigational Device Exemption (IDE) when the IRB concurs with the NSR determination of the Investigator/sponsor and approves the study. FDA documentation is not required. Therefore, both the sponsor and the Investigator are expected to comply with [21 CFR 812.2 \(b\)](#), the abbreviated FDA requirements for IDEs, as specified below. If the study is Investigator-initiated, then the Investigator is also acting as the sponsor.

[21 CFR 812.2 \(b\)](#): The following categories of investigations are considered to have approved IDEs unless FDA has notified a sponsor under 812.20(a) that approval of an application is required:

1. An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:
  - a. Label the device in accordance with [§812.5 Labeling of Investigational devices](#).
  - b. Obtain IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval
  - c. Ensure that each Investigator participating in an investigation of the device obtains from each subject under the Investigator's care, informed consent under [21 CFR 50](#) and documents it, unless documentation is waived by an IRB under [21 CFR 56.109 \(c\)](#).
  - d. Comply with the requirements of [21 CFR 812.46](#) with respect to monitoring investigations
  - e. Maintain 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)
  - f. Ensure that participating Investigators maintain the records required by 21 CFR 812.140 (a)(3)(i) and make the reports required under [21 CFR 812.150 Reports](#) and
  - g. Comply with the prohibitions in [21 CFR 812.7](#) against promotion and other practices.

## **Studies of Custom Devices**

1. IRB approval for use of a custom device is not required when the use is solely for **clinical care**.
2. If a custom device will be used in a research project to collect safety and effectiveness data for FDA approval of commercial distribution, an Investigator must submit the research project to the IRB. A Convened IRB will review the research project using the criteria described in this document and the document [IRB Initial Approval of Research](#).

## Investigational Device Exemptions [21 CFR 812](#)

An investigation involving a device is exempt from IDE regulations if it involves the following categories of devices:

1. The device, other than a transitional device, was in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

**OR**

2. The device, other than a transitional device, was introduced into commercial distribution on or after May 28, 1976 and the FDA has determined the device 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.

**OR**

3. The device is a diagnostic device, and the sponsor complies with applicable federal requirements, 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 of the diagnosis by another, medically established diagnostic product or procedure

**OR**

4. The device is 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 subjects at risk.

**OR**

5. The device is a custom device used solely for clinical care. IRB approval for use of a custom device is not required when the use is solely for **clinical care**.

## Emergency Use

An emergency use of an investigational device by a clinician without prior IRB review and approval is permitted under [21 CFR 56.104\(c\) - Emergency Use of a Test Article](#). The one-time emergency use of an investigational device must be reported to the IRB via the electronic system within 5 days of the use.

## Sponsor-Investigator Resources

The Mayo Clinic [Office of Research Regulatory Support \(ORRS\)](#) provides assistance to Mayo Clinic Investigators working on FDA-regulated research involving drugs, biologics, devices or other test articles. It is a centralized resource for information, expertise, and support related to the conduct of clinical research under Investigator-initiated INDs or

IDEs. See IRB document [Reporting\\_Requirements\\_for\\_Sponsor-Investigators\\_Conducting\\_Investigational\\_New\\_Drug\\_\(IND\)\\_or\\_Investigational\\_Device\\_Exemption\\_\(IDE\) Research](#).

## Troubleshooting

N/A

## Procedural Notes

N/A

## Related Documents

[Control of Investigational Devices Policy](#)

[Reporting Requirements for Sponsor-Investigators Conducting Investigational New Drug \(IND\) or Investigational Device Exemption \(IDE\) Research](#)

[Emergency Single-Case Use of an Investigational Device, Drug or Biologic Product](#)

[IRB Initial Approval of Research](#)

[Modifications to Previously Approved or Exempt Research](#)

[Continuing Review of Research Projects](#)

[Software as a Medical Device](#)

[General Wellness: Policy for Low Risk Devices](#)

## Definitions

**Device:** An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other, similar, or related article, including a component part or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- 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
- 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 any of its primary intended purposes.

**Investigational Device:** An investigational medical device is one that that does not have FDA approval for its clinical indication or for its proposed use in the study, and its use is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. This policy applies to investigational devices whether they are determined to be significant risk or non-significant risk.

**Investigational Device Exemption (IDE):** Application document submitted to the FDA proposing human clinical research to study an unapproved significant risk device, or a cleared or approved device for use other than its approved indication or intent. FDA grants permission so a device that otherwise would be required to comply with a performance standard or to have pre-market approval can be shipped lawfully for the

purpose of conducting investigations of that device. This FDA permission is evidenced by the assignment of an IDE number.

**Significant Risk (SR) Device Study:** A study of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and: 1) is intended as an implant; 2) is used in supporting or sustaining human life; or otherwise prevents impairment of human health; 3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

**Non-Significant Risk (NSR) Device:** A study of a device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of participants.

**Abbreviated Investigational Device Exemption Requirements:** The FDA considers an investigation of a non-significant risk device to have an approved Investigational Device Exemption when the IRB concurs with the initial non-significant risk determination of the sponsor/Investigator and approves the study. Therefore, both the sponsor and the Investigator are expected to comply with [21 CFR 812.2 \(b\)](#), the abbreviated FDA requirements for IDEs. If the study is Investigator-initiated, then the Investigator is also acting as the sponsor.

## References

[21 CFR 812.2 \(b\)](#)

[21 CFR part 812 Investigational Device Exemptions](#)

[21 CFR 812.2 \(b\)](#)

[21 CFR 812.7](#)

[21 CFR 812.46](#)

[21 CFR 812.140 \(b\)](#)

[21 CFR 812.150 \(b\)](#)

[21 CFR 812.150 Reports](#)

[21 CFR part 50 Protection of Human Subjects](#)

[21 CFR part 56 Institutional Review Boards](#)

[21 CFR 56.104\(c\) - Emergency Use of a Test Article](#)

[21 CFR 56.109 \(c\)](#)

[45 CFR part 46 Protection of Human Subjects](#)

[46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research](#)

[56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research](#)

[§812.5 Labeling of Investigational devices.](#)

## Owner

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## Contact

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## Revision History

<b>Date</b>	<b>Synopsis of Change</b>
06/22/2021	Scheduled review. Transferred to standardized template. Minor revisions. Included related documents to include Software as a Medical Device (SAMD) and general wellness devices.
10/19/2017	Minor revision. Updated the following definitions per Glossary review: Investigational Device, Investigational Device Exemption (IDE), Non-significant Risk (NSR) Device Study, and Significant Risk (SR) Device Study.
03/20/2017	Scheduled review. Under Related Documents, added 'Policy' to 'Control of Investigational Devices'.