

Abbreviated IDE Requirements (US)

Summarized in this document are the FDA regulations specific for when a device is not a significant risk. In addition, a vast majority of clinical trials must also comply with ICH E6 ([link](#))

Abbreviated IDE Applicability (21 CFR 812.2)

- Investigation of a device that is not significant risk and not banned from use
- 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
- Informed consent and documentation of informed consent from all subjects
- Follows all regulations below

Oversight (21 CFR 812.46)

- Oversight of Investigators
 - Ensure each PI obtains IRB approval
 - Ensure each PI obtains informed consent
- Create an Investigational Plan¹
 - Protocol
 - Purpose- name each investigational device and drug, intended use, study objectives, and anticipated duration
 - Device Description- describe each component, principle operation, and anticipated changes
 - Risk Analysis – assessment and supporting evidence of why the study does not pose significant risk
 - Monitoring Plan
 - Labeling
 - ICF
 - IRB Information
- Disseminate study protocol and train each PI

Prohibition of Promotion and Other Practices (21 CFR 812.7)

- Do not promote an investigational device, until after FDA has approved/cleared the device
- Do not commercialize the device by charging subject or investigators for a device a price larger than necessary to recover costs of manufacture, research, development and handling
- Do not unduly prolong an investigation. If a class II or III device, and the study data indicates that approval cannot be justified, or that the device will not comply with an applicable performance standard (or an amendment to that standard), the sponsor should promptly terminate the investigation.

Monitoring/Safety (21 CFR 812.46)

- Create and follow Monitoring plan²
- Ensure PIs comply with signed agreement and investigational plan
- Document in protocol or stand-alone document anticipated adverse device effects (ADEs), including their frequency and severity²
- Capture, document, and evaluate ADEs and immediately evaluate UADEs³ encountered during study conduct

Reporting [812.150(b)(1)-(3) & (5)-(10) & 812.150(a)(1), (2), (5), & (7)]

- Submit unanticipated adverse device effects ([21CFR 812.3s](#)) to FDA and IRB
- Report to FDA and IRB, if an investigator failed to obtain informed consent
- Report to FDA if an IRB withdraws approval for the study
- Submit yearly progress reports to IRB
- Notify IRB and FDA of any device recall, repair, or disposal
- Submit final report on the study to IRB within 6 months of study completion
- If the device determination is changed to significant risk (NSR to SR), notify FDA

Records⁴ [812.140(b) (4) and (5) and 812.140(a)(3)(i)]

- Document all correspondence with, for example, another sponsor, a monitor or vendor, an investigator, an IRB, or FDA, including required reports.
- Document device accountability; i.e. records of shipment and disposition of the device
- Document rationale for why the device presents non-significant risk (NSR)²
- Document adverse device effects (whether anticipated or unanticipated) and complaints
- Document names and addresses of all PIs and all IRBs²
- Document the device manufacturer's level of GMP compliance (requirements in [21 CFR 820](#))²
- Have on file signed Investigator Agreement(s)⁵

Labelling (as per 21 CFR 812.5)

- Ensure the device is appropriately labeled with the following statement: "CAUTION-- Investigational device. Limited by Federal (or United States) law to investigational use."
- The labeling of an investigational device shall not bear any statement that is false or misleading and shall not represent that the device is safe or effective for the purposes for which it is being investigated

Clinical Trials.gov (42 CFR 11)

Register, maintain, and provide results of your trial listing on Clinical Trials.gov. Small clinical trials to determine feasibility of a device product, or clinical trials to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes are excluded.

Additional consideration⁶

An IDE application submission to the FDA could be required for all devices, including your non-significant risk device when:

- Noncompliance with Abbreviated IDE regulations requires application to be submitted
- Risk of device is higher than initially evaluated

[1] Investigational Plan contains most components of 21 CFR 812 requirements, template available with OCR

[2] Compliance with these elements are contained in the investigational plan

[3] *Unanticipated adverse device effect* means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

[4] *Retention period*. An investigator or sponsor shall maintain the records required during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.

[5] Investigator Agreement template available with OCR

[6] Please see OCR SSU regarding this.