

## Exemption from IDE Regulations Guidance

### Is the protocol subject to IDE regulations?

1. Is the device being used as a medical device on the protocol? Assess how the device is being used on the protocol.

If no, the protocol is not subject to IDE regulations; however the sponsor- investigator is still responsible for ensuring the quality and safety of the product for the trial in the subject population.

Not sure? Penn Medicine investigators may contact OCR. Alternatively, the sponsor or sponsor-investigator can email [DeviceDetermination@fda.hhs.gov](mailto:DeviceDetermination@fda.hhs.gov) to receive informal feedback regarding whether a product constitutes a medical device. Please also see [How to Determine if Your Product is a Medical Device](#) for more guidance from the FDA.

Please note that computer software (e.g., AE, algorithms, etc.) can be considered a medical device when it interacts with the medical record and/or when it is used in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions.

2. If the device is being used as a medical device, is the protocol a clinical investigation to determine safety or effectiveness of the device?

- In other words, is the device under investigation on the protocol?
- Are any of the protocol objectives to study the safety OR efficacy of the device? Is the device being validated? Is the predictive ability of the device being investigated?

If yes, this is an applicable clinical trial under IDE regulations (21 CFR 812.2) and an assessment of whether the study is exempt from IDE regulations should be obtained.

Applicable clinical investigations may include:

- Studies to gain initial safety and effectiveness information to support further study
- Pivotal studies to support marketing application to FDA for a new device or a new use of a marketed device
- Sponsor-investigator studies of unapproved devices or new intended use of approved device even if no marketing application is planned.
- Feasibility studies to preliminary information regarding safety and potential for effectiveness
- Feasibility studies to Inform device design; refinements to device for future study

**Note: Studies that use a medical device off label are considered to be under investigation and may be subject to IDE regulations and required to follow ICH Good Clinical Practices. This applies even if the purpose of the protocol is not to determine the safety/effectiveness of the device.**

3. Does the study meet the criteria for an exemption from IDE requirements as outlined in 21 CFR 812.2(c)?

- A medical device in commercial distribution that is used or investigated in accordance with the indications in labeling.
- A diagnostic device, if one complies with applicable requirements in 809.10(c) and if the testing:
  - (i) Is **noninvasive**,
  - (ii) **Does not require an invasive sampling** procedure that presents significant risk,
  - (iii) **Does not** by design or intention **introduce energy** into a subject, and
  - (iv) Is **not used as a diagnostic procedure without confirmation** of the diagnosis by another, medically established diagnostic product or procedure.

Diagnostic Device: Diagnostic devices are devices used to identify the nature or cause of a certain phenomenon, usually related to a medical condition. Examples of diagnostic devices are in vitro diagnostics, lab developed tests, MRI, temperature sensors, ECG, EEG, etc.

Applicable Requirements in 21 CFR 809.10(c)

- For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."
- For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

Energy: Sound, light, magnetism, radiation, or biofields

Used as a diagnostic procedure: Either the results are returned to participants, OR the results are placed in the medical record, OR their care will change based on the results of the test/device.

Confirmation by a medically established diagnostic product or procedure: Is confirmed by some other medically established device or usual care procedure.

- A medical device undergoing **consumer preference testing**, if the testing is not for the purpose of determining safety or effectiveness **and** does not put subjects at risk.
- Testing of a **modification**, if the testing is not for the purpose of determining safety or effectiveness **and** does not put subjects at risk.
- Testing of a **combination of two or more medical devices in commercial distribution**, if the testing is not for the purpose of determining safety or effectiveness **and** does not put subjects at risk.



- A custom medical device as defined in 812.3(b), unless the device is **being used to determine safety or effectiveness for commercial distribution.**

Custom Device: Is created or modified in order to comply with the order of an individual physician or dentist (or other specially qualified person). It is not generally available in finished form through labeling or advertising by the manufacturer. It is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat. It is intended to either meet the special needs of a physician or dentist in the course of their professional practice OR intended for use by an individual patient named in the order of a physician or dentist.

If the study meets the exemption criteria, the study is considered exempt from IDE requirements.

If the study does not meet the exemption criteria, the study is not exempt from IDE requirements and requires an IDE: abbreviated (non-significant risk) or full application to FDA (significant risk). The next step is to determine the risk of the device, as used on the protocol.

**Note: Penn Investigators are not permitted to self-exempt from IDE regulations. Exemptions must be confirmed by the Penn Medicine Office of Clinical Research, the Penn IRB, or the FDA.**