
In vitro diagnostic (IVD) products are defined in FDA regulations at 21 CFR 809.3(a) as those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. IVD products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

Under FDA's IVD device regulations, the definition of "subject" includes individuals on whose specimens an investigational device is used; therefore, an IVD study using human specimens involves human subjects.

An IVD study is exempt from IDE regulations if the sponsor complies with labeling requirements at 21 CFR 809.10(c) and if the testing:

- is noninvasive;
- does not require an invasive sampling procedure that presents significant risk;
- does not by design 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.

Even if an IVD study is exempt from IDE regulations, other FDA regulations, at 21 CFR 50 and 56, still apply.

When an IVD study is not eligible for exemption from IDE requirements, the sponsor must make a significant/non-significant risk assessment (significant risk or non-significant risk) and obtain an approved IDE before a research may begin the investigation." IDE requirements depend on this assessment. For a significant risk device, the sponsor must have an IDE application approved by FDA and follow all IDE regulations at 21 CFR 812. For a non-significant risk device, the sponsor must meet the abbreviated requirements at 21 CFR 812.2(b), including monitoring, IRB review and approval of the study, and compliance with informed consent requirements.

The goals of IVD studies are the same as those of other device studies, even if the IVD study is exempt from most IDE requirements at 21 CFR 812.2(c)(3). FDA recommends that the sponsor and the investigators conduct an IVD device study in order to produce valid scientific evidence demonstrating reasonable assurance of the safety and effectiveness of the product, while protecting the rights and welfare of subjects.

In some cases, clinical investigations of therapeutic products (such as drugs or biologics) use investigational IVDs to guide the management of subjects, including

- to select or classify subjects
- to assign subjects to therapeutic product arms or doses
- or to monitor responses to treatment

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Use of an investigational IVD in a therapeutic product study may pose additional risk to subjects, and such studies are subject additional requirements and oversight.

Contact the IRB for more information about research involving in vitro diagnostic products.

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