What is FDA Research?

The Food and Drug Administration's (FDA) research goal is to anticipate and solve scientific and technical challenges before they become obstacles to our mission. The application of this research to figure out these many challenges is the common thread woven throughout all FDA's work. FDA's unique role is to close the gaps that basic discovery research has not addressed and successfully tackle specific regulatory challenges.

"Research" as defined by FDA is means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

- "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
- "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]

For more information see the **Food and Drug Administration**.

If you are unsure if you study needs IRB approval ask yourself these questions:

- Does the activity involve the use of a drug (including an approved drug or an over-the-counter drug), other than the use of an approved drug in the course of medical practice?
- Does the activity involve the use of a medical device (including an approved medical device), other than the use of an approved medical device in the course of medical practice? (Note that medical devices generally include devices intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, and devices intended to affect the structure or any function of the body of humans or other animals.
- Will data be submitted to the FDA or held for their inspection?

If the answer to one of the above questions is "yes," then you will need IRB approval to proceed.

Other Resources

Texas Health IRB Website

Frequently Asked Questions

Texas Health Policy for Protection of Human Research Subjects

Office for Human Research Protections (OHRP)

U.S. Food and Drug Administration (FDA)