IDE Overview

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Confused about the need to file an IDE? Think your study may be exempt? Not sure where to start? You are not alone. This website will help faculty navigate the process of developing a Sponsor-Investigator IDE. The information provided pertains to some Class II and all Class III devices that pose risk, have a new intended use, or employ a new, unique technology.

The sponsor of a Significant Risk (SR) device study is required to submit an IDE application to the FDA. The IDE allows the investigational device to be used in a clinical study in order to collect the safety and effectiveness data required to support a marketing application.

Use the IDE Decision Tool to help you determine if an IDE is required. While the first step is a self-assessment of whether an IDE is needed, the IRB serves as a first-level review as designated by FDA. FDA makes the ultimate regulatory decision, if needed.

Please refer to the final guidance "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff."

Need assistance or have regulatory questions? Please contact ResearchGo.

Mobile Medical Applications

Developing a mobile medical app? The FDA has issued guidance on "Mobile Medical Applications" to clarify the subset of mobile apps to which the FDA intends to apply its authority. You can also contact FDA for a question about your Mobile Medical App.

The Federal Trade Commission (FTC) has created a web-based tool to help developers of health-related mobile apps understand what federal laws and regulations might apply to them.

Artificial Intelligence and Machine Learning in Software as a Medical Device

Artificial Intelligence (AI) and machine learning (ML) technologies have the potential to transform health care. On March 15, 2024, the FDA published the "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together," which represents the FDA's coordinated approach to AI. This paper is intended to complement the "AI/ML SaMD Action Plan" published in January 2021.

If you have questions about artificial intelligence, machine learning, or other digital health topics, ask FDA about digital health regulatory policies.

More Device Guidance

Guidance is available for Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.

In 2022, the FDA issued updated guidance regarding Medical Device Data Systems (MDDS), Medical Image Storage Devices, and Medical Image Communication Devices.

Information for the eCopy Program for Medical Device Submissions can be found here: eCopy Program for Medical Device Submissions.

Please contact FDA Device Advice or ResearchGo for assistance or more information.

Last updated: 10 Mar 2025

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