# IRB Tip Sheet: Digital Heath Tools - Device Software Functions and Mobile Medical Applications

**What is Digital Health?**

The broad scope of digital health includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. Digital health technologies use computing platforms, connectivity, ***software***, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They may also be used to develop or study medical products.

**When does software become a medical device?**

Software as a Medical Device is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

The FDA uses the term "software functions." This is because the *intended use* of software is what the FDA uses to determine if it is a medical device. The term "function" means a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product. A single software product can have multiple functions.

Device software functions may be deployed on mobile platforms, other general-purpose computing platforms, or in the function or control of a hardware device. This means that the term "software functions" includes the functions of mobile applications or "apps."

*Note that a mobile application is considered a medical device when it is used an accessory to a regulated medical device or used to transform a mobile platform into a regulated medical device.*

**When does software become FDA regulated?**

FDA intends to apply its regulatory oversight to software functions that meet the definition of a *medical device* and whose *functionality* could pose a *risk* to a patient's safety if the device were not to function as intended. In other words, they pose potential risks to the public health if they fail to function as intended.

How the FDA intends to apply it regulatory oversight is communicated in the FDA guidance document titled, Policy for Device Software Functions and Mobile Medical Applications (2022).

**How to determine if a software function is considered a medical device under FDA regulations?**

The FDA's website Digital Health Policy Navigator is a tool to help in determining whether software functions are potentially the focus of the FDA's oversight. The Navigator aggregates the information from various FDA regulations, policy, and guidance documents. The results are not a formal determination but provide relevant information and recommendations. If a software has multiple functions, then each function should be analyzed separately.

**What are the different levels of FDA oversight related to software functions (Click links for examples)?**

- ❖ Device software functions under FDA regulatory oversight
  - These types of software meet the definition of device in the Federal Food, Drug, and Cosmetic Act and their functionality poses a risk to a patient's safety if the software were to not function as intended.
  - *IRB Considerations:* The requirements for device determinations by the IRB are the same as other FDA regulated medical devices. Protocol documentation is also the same as other FDA regulated medical devices.
- ❖ Software functions for which the FDA intends to exercise enforcement discretion
  - Even though these software functions may meet the definition of a medical device, the FDA intends to exercise enforcement discretion for these software functions, because they pose a lower risk to the public.
  - *IRB Considerations:* As the FDA is not applying the device regulations to these types of devices, the IRB does not need to apply the device regulations and make a determination.
- ❖ Software functions that are not medical devices
  - Since they are not medical devices, they are not FDA regulated.
  - *IRB Considerations:* No need for IRB device determinations needed since the software functions are not FDA regulated.