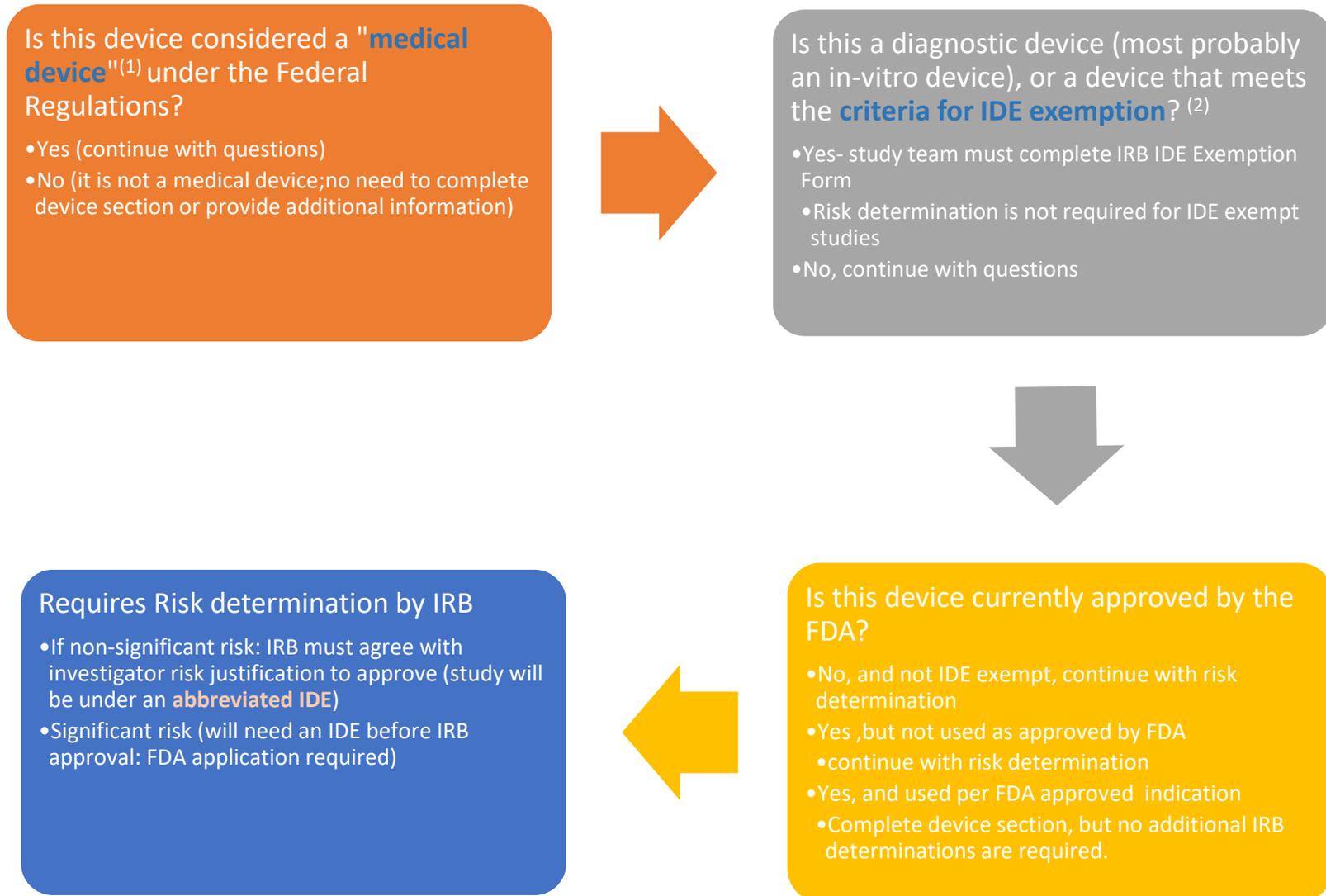


Decision chart for Devices used in Human Subject Research Studies looking at Safety and Efficacy (Without existing IDEs)



(1) Medical Device

A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

(2) IDE Exempt Investigations

All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from [21 CFR 812](#) are described in §812.2(c) of the IDE regulations. Studies exempt from the IDE regulations include:

1. a legally marketed device when used in accordance with its labeling
2. a diagnostic device if it complies with the labeling requirements in §809.10(c) and if the testing:
 - a. is noninvasive;
 - b. does not require an invasive sampling procedure that presents significant risk;
 - c. does not by design or intention introduce energy into a subject; and
 - d. is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure;
Additional guidance for an in vitro diagnostic device studies can be found in "[Regulating In Vitro Diagnostic Device \(IVD\) Studies.](#)"
3. consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
4. a device intended solely for veterinary use;
5. a device shipped solely for research with laboratory animals and contains the labeling "CAUTION – Device for investigational use in laboratory animals or other tests that do not involve human subjects."