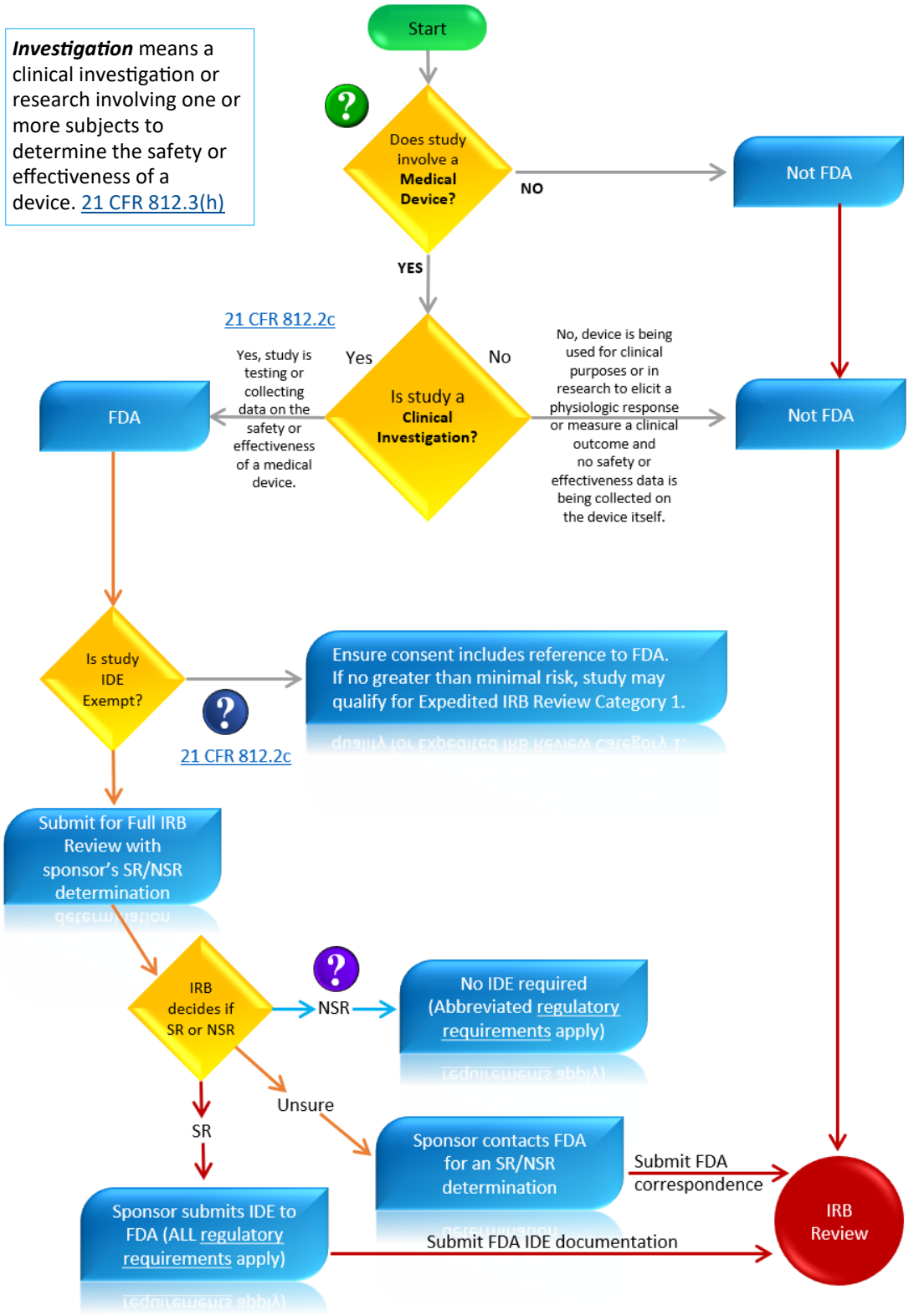
Medical Device Trials

Investigation means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device. 21 CFR 812.3(h)



Definition:

A Medical Device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article, including any component, part, or accessory, & is—

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man, or
- intended to affect the structure or any function of the body of man
- and does not achieve its primary intended purposes through chemical action or being metabolized. See FDA FAQ

Examples of IDE Exempt Trials

must meet all applicable conditions

- Study of device used in accord with FDA approved labeling and indications* and no intent to report to FDA in support of new indication or label change.
- An In-vitro device that meets IDE exclusion criteria.
- Device Software & Mobile Medical Apps for which FDA intends to exercise enforcement discretion.

The convened IRB considers device AS USED IN STUDY when making SR/NSR determination. The investigator should provide manufacturing information, labeling or other material describing FDA-approved indications.

Significant Risk (SR)

Device as used in study presents a potential for serious risk to the health, safety, or welfare of a subject, or an implant, or designed to support or sustain human life, or substantial importance in diagnosing, curing, mitigating, or treating disease, or preventing impairment of human health.
SR device studies require an IDE submission to FDA.

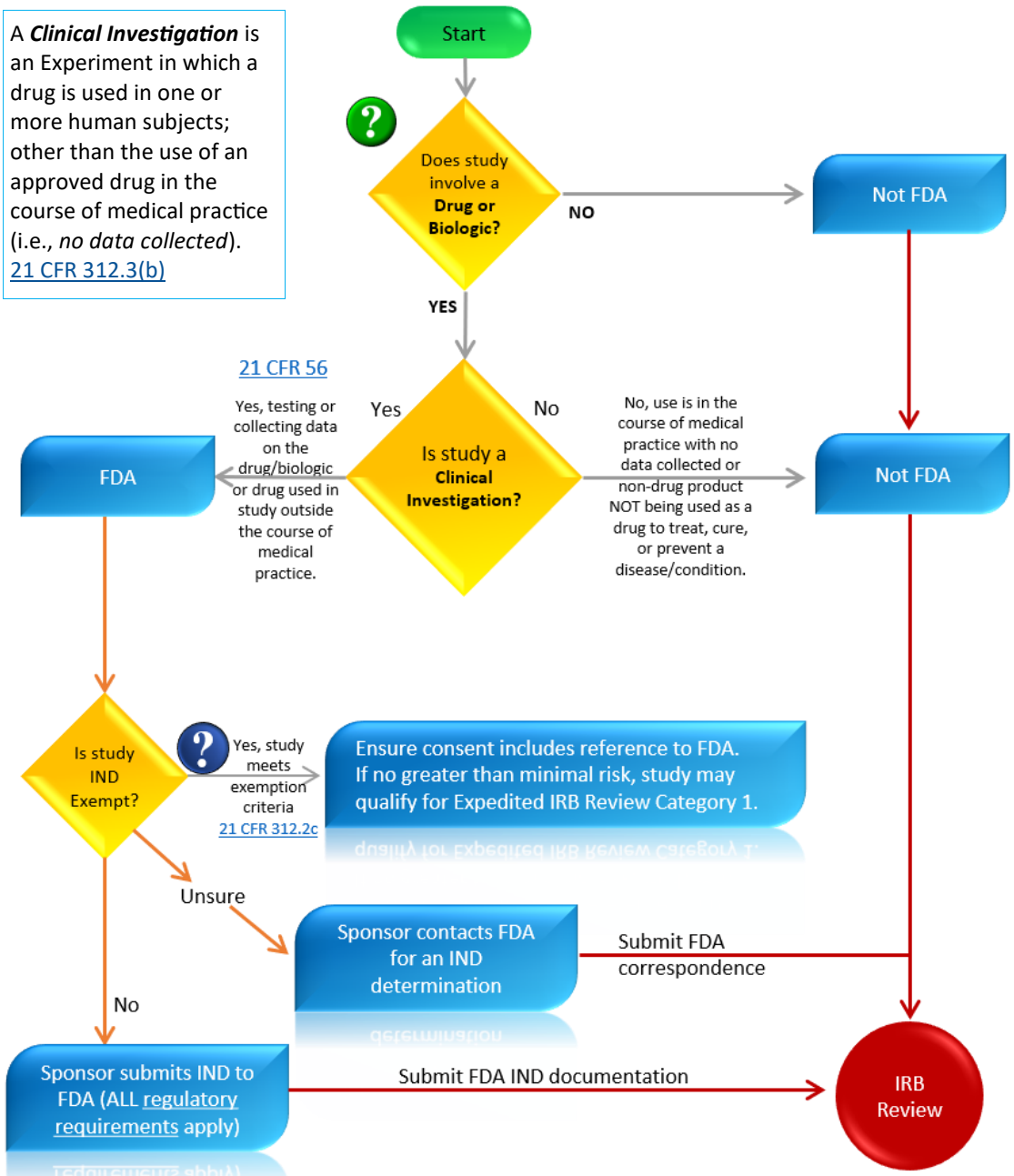
NON Significant Risk (SR)

Does NOT meet any criteria in significant risk definition. Involves a level of risk that doesn't warrant review by FDA, so no IDE required. IRB acts as surrogate for FDA. Sponsor or Sponsor-Investigator have abbreviated IDE responsibilities.

For additional detail, see the IRB Review Of Medical Device Research Guidance

Drug/Biologic Trials

A ***Clinical Investigation*** is an Experiment in which a drug is used in one or more human subjects; other than the use of an approved drug in the course of medical practice (i.e., *no data collected*). 21 CFR 312.3(b)



Definitions

A Drug is "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body.

A biologic is a virus, toxin, vaccine, blood, blood derivative, protein, gene therapy, growth factors, cytokines, monoclonal antibodies, and other organic compounds used to prevent, treat, or cure disease.

Examples of IND Exempt Trials

Unapproved use of an approved drug *if all criteria met:*

- *Lawfully marketed in US;*
- *Not in support of new indication*
- *Not to change label or marketing*
- *Does not involve route of administration, dose, population that significantly increases risk or decreases tolerability*
- *Has IRB approval & informed consent & not done for promotion.*

Dietary Supplement *if study designed* only to reduce risk of a disease; evaluate structure or function of the body; support a new or expanded health claim, **and** EXCLUDES individuals less than 12 months old, those with altered immune systems, or serious or life-threatening medical conditions.

FDA IND Exempt Guidance

Dietary Supplement FAQ
Studies Involving E-Cigarettes

In making a determination on the need for an IND, the IRB considers manufacturer information & whether study measures therapeutic effect or affect on structure or function of the body.

Additional Guidance

Summary of FDA Regulations on Exemption from IND Requirements
IND Exemptions for Studies in Marketed Drug or Biologic for the Treatment of Cancer