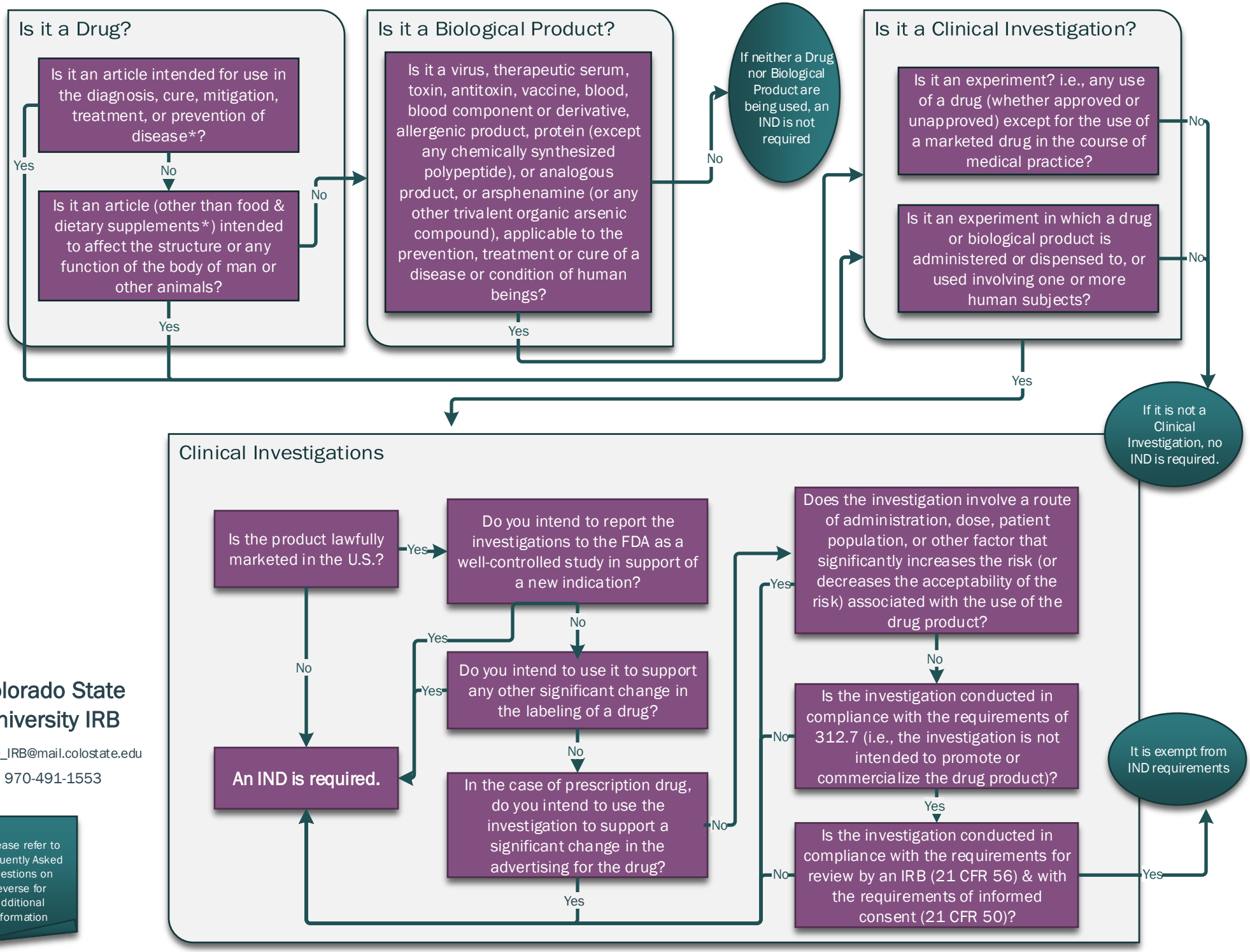
Does the Study Require an Investigational New Drug Application (IND) from the FDA?



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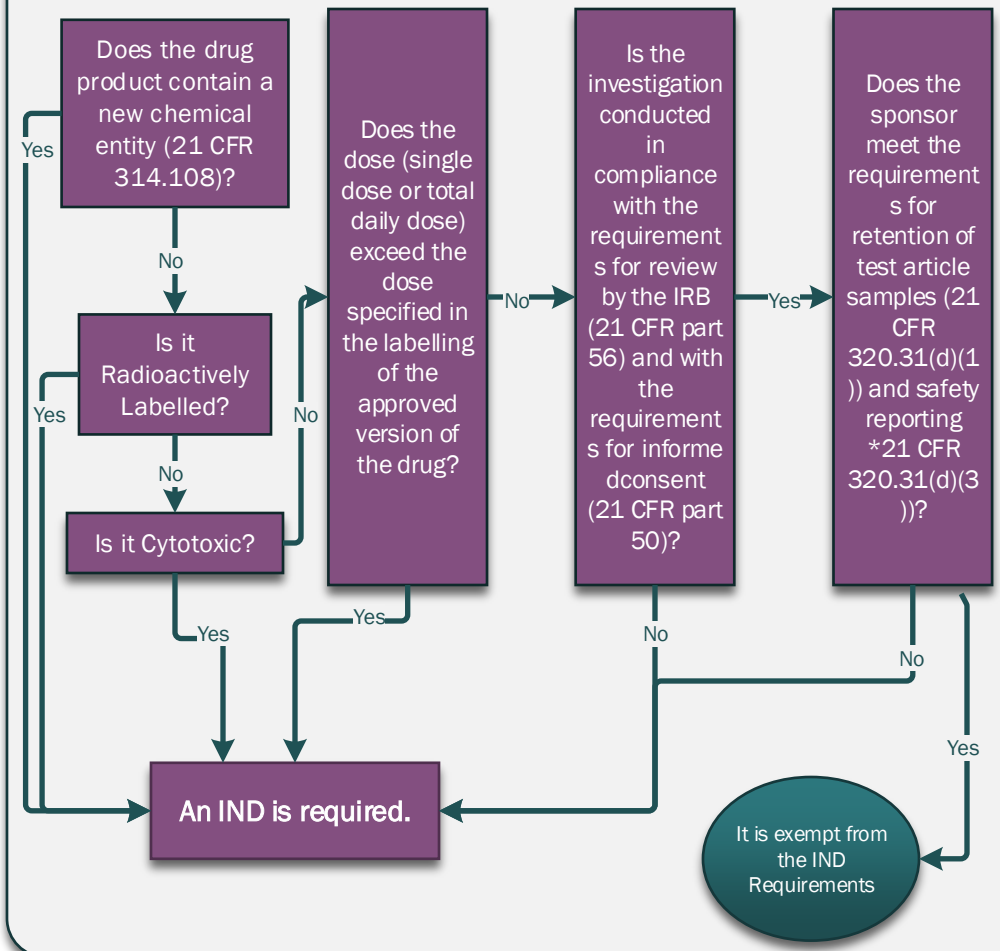
*Please refer to Frequently Asked Questions on reverse for additional information

Is an IND Needed for a Bioavailability and Bioequivalence Study?



IRB Responsibilities

1) Evaluating the investigator's qualifications

2) Assessing adequacy of research sites

3) Questioning or determining whether and Investigational New Drug (IND) is needed. Initial determination should come from the Sponsor or Sponsor-Investigator.

Frequently Asked Questions

1) Are bacterial vaccine, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal an-tibodies considered Biological products? Yes.

2) Is the definition for a drug limited to compounds intended for therapeutic purposes? No. The definition also includes compounds (other than foods and dietary supplements) intended to affect the structure or function of the body, without regard to whether the compound is intended to influence a disease process. For example, the definition includes compounds administered to healthy individuals to prevent pregnancy or treat male pattern baldness.

3) Is a dietary supplement considered a drug? That depends. A dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body and not intended for therapeutic purpose. If there is a clinical investigation intended to evaluate if a dietary supplement has the ability to diagnose, cure, mitigate, treat, or prevent a disease, an IND is required under part 312. For example, a clinical investigation designed to study the relationship between a dietary supplement's effect on normal structure or function in humans (e.g. guarana and maximal oxygen uptake) or to characterize the mechanism by which a dietary supplement acts to maintain such structure or function (e.g. fiber and bowel regularity) would not need to be conducted under an IND. However, a clinical investigation designed to evaluate a dietary supplement's ability to prevent osteoporosis or to treat chronic diarrhea or constipation would need to be conducted under an IND.

4) Is food considered a drug? That depends. A food used as such (i.e., primarily for taste, aroma, or nutritive value) and not for therapeutic purpose or to affect the structure or function of the body, other than by providing nutrition, is not a drug. For studies intended to evaluate the effects of a food, the analysis for whether an IND is needed turns on the intent of the clinical investigation. A food is considered to be a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," except that a food may bear an authorized health claim about reducing the risk of a disease without becoming a drug. The FDA regulates conventional foods (including baby formula) that are intended to affect the structure or function of the body as foods, not drugs, as long as the intended structure or function effect derives from the product's character as food – its taste, aroma, or nutritive value. For example, a clinical investigation intended only to evaluate the nutritional effects of food (including medical foods) would not require an IND, but an investigation intended to evaluate other effects of a food on the structure or function of the body would. A study of the effect of iron on hemoglobin levels in which subjects were fed beef or lamb as a source of iron would not require an IND, but a study of the effect of soy isoflavones on bone metabolism would.

5) Is an IND required before administering food or other products containing substances generally recognized as safe (GRAS)? A clinical investigation of a GRAS substance that is intended to evaluate the products ability to diag-nose, cure, mitigate, treat, or prevent disease requires an IND under part 312, unless the substance to be studied is also a lawfully marketed drug and the clinical investigation meets the criteria for exemption under 21 CFR 312.2(b).