The Pre-IND Process

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Review the five requirements in the IND Exemptions below to determine if your study qualifies for exemption from an IND (21 CFR 312.2).

Still not sure? Start with the IND Decision Tool. Pay particular attention to requirement #3. The FDA Draft Guidance Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted without an IND provides more detail on a range of topics, including the process for consulting with FDA. In addition, please consult with the IRB to determine whether a formal letter from FDA is required to document the IND Exemption.

If you think an INTERACT meeting or pre-IND meeting with the FDA is warranted, please contact ResearchGo for assistance. Templates for a meeting request letter and meeting briefing packages are provided below.

- IND Exemption Letter
- Pre-IND Consultation Contact List
- Request for Pre-IND Meeting
- Pre-IND Briefing Package
- INTERACT Meeting Briefing Package
- INTERACT Meeting Request - CBER
- INTERACT Meeting Request - CDER
- Types of Meetings with the FDA

IND Exemptions

A drug that is lawfully marketed in the United States is exempt from the requirements for an IND if all of the following apply:

- The investigation is not intended to be reported to the FDA in support of a new indication for use or any other significant change in the labeling for the drug.
- The investigation is not intended to support a significant change in the advertising for a prescription drug product.
- The investigation does not involve a change in route of administration, dosage level, or patient population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with use of the drug product.
- The investigation is conducted in compliance with the requirements for IRB review (21 CFR 56) and informed consent (21 CFR 50).
- The drug may not be represented as safe or effective for the purposes for which it is under investigation, nor may it be commercially distributed or sold.

For additional information about whether or not an IND is required for a cancer therapy drug, contact the NCI Regulatory Affairs Branch.

Need assistance or have regulatory questions? Please contact ResearchGo.

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