IND Exemptions

Research Compliance Office

Stanford University

October 2023

IND Exemptions – Brief Overview

The drug used in the study/investigation is **lawfully marketed** in the U.S. and:

- Is not intended to support FDA approval of a **new indication** or a **significant change in the product labeling**.
- Is not intended to support a **significant change in** the **advertising** for the product.
- Does not involve a **route of administration** or **dosage level** or use in a **patient population** or other factor that **significantly increases the risks** (or decreases the acceptability of the risks) associated with the use of the drug product.

IND Exemptions – Brief Overview

The drug used in the study/investigation is **lawfully marketed** in the U.S. and:

- Is conducted in compliance with IRB and informed consent regulations set forth in 21 CFR parts 56 and 50.
- Is conducted in compliance with § 312.7 (promotion and charging for investigational drugs).

IND Exemptions – eProtocol

Protocol Information section 6b:

Please list in the table below all commercial drugs, reagents or chemicals to be administered to subjects.

Commercial Drugs, Reagents, Chemicals

	Drug Name	Source	IND Regulations	Manufacturer	Dosage
☐	Ciprofloxacin	Pharmacy	Yes	Bayer	500 mg po BID x 5 days

IND Exemption

* ◉ Yes ○ No	Is this new and different uses of this commercially available drug, reagent or chemical?
◉ Yes ○ No	Are all of the IND statements shown below true?

Questions?