

# Charging for Investigational Drugs in Clinical Trials

Office of Research Compliance

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# Old Rule: 21 C FR §312.7

- Charging for Investigational Drug in Clinical Trials conducted under an IND was rarely permitted.
  - Required prior written approval of FDA
  - Sponsor had to provide full written explanation of why “charging is necessary in order for sponsor to undertake or continue the clinical trial.”
  - FDA default was to consider distribution of drugs to test subjects as part of sponsor’s normal cost of doing business.

# New Rule: 21 CFR §312.8

- Rule covers charging for Investigational Drugs in Clinical Trial and in Expanded Access Use (i.e., use of investigational drug for treatment of patient or group of patients outside of the context of a clinical trial).

# Charging for IND in Clinical Trial

- New rule expressly covers charging for unapproved Investigational New Drug AND investigational use of an FDA approved drug.
- Generally, Sponsor must have FDA approval to charge for use of Sponsor's approved drug in clinical trial when Sponsor provides drug.
- **EXCEPTION:**
  - Sponsor does not need to follow rule to charge for use of its approved drug for an approved use in a clinical trial.

# Charging for IND in Clinical Trial

- EXCEPTION: Sponsor does not have to follow new rule to charge for an FDA approved drug obtained from another entity not affiliated with the sponsor when approved drug is being used as part of the clinical trial.
  - EXAMPLE: FDA Authorization not required when when FDA approved drug is used in trial as a control, or in combination with another drug or for a new unapproved use AND approved drug is obtained from an entity other than the Sponsor (e.g., drug is dispensed through in-patient or out-patient pharmacy).

# Charging for IND in a Clinical Trial

- In order to charge for an investigational drug, the Sponsor must obtain FDA written authorization.
- In order to obtain FDA authorization, Sponsor must make a submission to FDA that demonstrates that all elements in 312.8(b) are met.
- Amount that Sponsor charges must be based on Sponsor's direct costs (e.g., raw materials, labor, etc.) and cannot include indirect costs.
- Authorization can last up to one year and must be renewed by FDA to continue past one year.
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# Example

- Sponsor Drug Company provides non-FDA approved Drug A to PI at Emory to conduct a study on Drug A. Sponsor Drug Company asks PI to pay for Drug A. Sponsor Drug Company must have FDA's written authorization in order to charge for Drug A.

# Example

PI is Sponsor-Investigator of Clinical Trial re. FDA approved Drug B. Trial looks at whether Drug B can be used for unapproved use. Sponsor-Investigator writes script for subjects to obtain Drug B from pharmacy. Sponsor-Investigator may charge for Drug B without having to get FDA written approval.