Charging by the sponsor for an investigational drug under an Investigational New Drug (IND) is not permitted without prior written authorization from the U.S. Food and Drug Administration (FDA) in compliance with 21 CFR 312.8. This includes investigational use of a sponsor’s approved drug under an IND. If the sponsor is proposing to charge for the investigational drug, the prior written authorization from the FDA must be submitted to the Institutional Review Board (IRB) as part of the initial IRB application. If the FDA withdraws authorization to charge for the investigational drug, the principal investigator must notify the IRB immediately and submit a revision to modify the IRB approved protocol.

Sponsors who obtain an approved drug from another entity not affiliated with the sponsor for use as part of the clinical trial evaluation (e.g. in a clinical trial of a new use of the approved drug, for use of the approved drug as an active control) are not subject to the requirements in 21 CFR 312.8 and prior written authorization from the FDA is not required. 21 CFR 312.8(a)(1).

The requirements under 312.8 also do not apply to clinical investigations exempt from IND requirements under 312.2(b).

For an investigational device, charging subjects or investigators a price larger than necessary to recover costs of manufacture, research, development, and handling is not permitted. 21 CFR 812.7(b). If a sponsor requests and receives approval for a waiver of 21 CFR 812.7(b), such approval should be provided to the IRB.