Charging for Investigational Products - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

This information sheet discusses FDA policy on allowing charges for the test articles in clinical investigations.

Decisions concerning charging subjects for investigational products are guided by professional ethics, institutional policies, and FDA regulations. The FDA informed consent regulations require the consent document to include a description of any additional costs to the subject that may result from participation in the research [21 CFR 50.25(b)(3)]. IRBs should ensure that the informed consent documents outline any additional costs that will be billed to study subjects or their insurance company as a result of participation in the study. IRBs should also ensure that any such charges are appropriate and equitable.

Because the regulations governing drugs and biologics vary from those governing medical devices, the Agency's position on charging for the test articles will be discussed separately. FDA does not prohibit charging the subjects for related treatment or for services.

1. **Charging for Investigational Medical Devices and Radiological Health Products**

   The Investigational Device Exemption (IDE) regulations allow sponsors to charge for an investigational device, however, the charge should not exceed an amount necessary to recover the costs of manufacture, research, development, and handling of the investigational device [21 CFR 812.7(b)]. A sponsor justifies the proposed charges for the device in the IDE application, states the amount to be charged, and explains why the charge does not constitute commercialization [21 CFR 812.20(b)(8)]. FDA generally allows sponsors to charge investigators for investigational devices, and this cost usually is passed on to the subjects.

2. **Charging for Investigational Drugs and Biologics**

   On August 13, 2009, FDA issued 21 CFR Part 312 and 316 Charging for Investigational Drugs Under an Investigational New Drug Application; Expanded Access to Investigational Drugs for Treatment Use; Final Rules. These rules address clinical studies conducted under an IND as well as treatment protocols and treatment INDs. These rules and the accompanying preamble are available at **http://edocket.access.gpo.gov/2009/pdf/E9-19004.pdf (http://edocket.access.gpo.gov/2009/pdf/E9-19004.pdf)**.

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