

Dr. Smith is an internist in private practice who works at an inner city clinic affiliated with a university hospital. He is also a member of the university faculty. Many of Dr. Smith's patients have type 2 diabetes mellitus and struggle with health care and other costs. Thinking about opportunities to better serve his patients and advance his career, Dr. Smith considers conducting clinical research in his office.

ACME is a respected pharmaceutical company that for decades has engaged in research, development, and production of widely used drugs. Several of ACME's oral agents for type 2 diabetes will soon go off patent. In an effort to retain its market share in this class of drugs, ACME wants to complete clinical trials expeditiously and obtain approval for its new oral hypoglycemic medicine. The company approaches Dr. Smith to be a coinvestigator in its multicenter clinical trial.



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ACME wants Dr. Smith to recruit one hundred patients for the study and will pay him \$750 for each patient he recruits and cover all expenses associated with the study, including laboratory tests, personnel, and equipment. Patients will receive free health care and medication during the study, which is expected to last three years. Dr. Smith fears, however, that once the trial is over and the medication is put on the market (assuming it is approved), many of his patients will not be able to afford it. He also has questions about the integrity of the ethical review process in this case. ACME is using a CRO to design the study, provide data analysis, and perform other tasks, including IRB review.

Dr. Smith believes the proposed research could bring much-needed attention and resources to his clinic. On the other hand, he also recalls that the university has had difficulty recruiting local patients for clinical trials. Some of his patients have expressed mistrust of the university and the health care system. Would asking them to participate in a trial jeopardize their trust in him?

New England Journal of Medicine
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The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Federal Register

Annals of Internal Medicine

Hastings Center Report

Journal of the American Medical Association

Preventing Chronic Disease