



Highlights of [GAO-09-448T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Millions of Americans enroll in clinical studies of experimental drugs and medical devices each year. Many of these studies are meant to demonstrate that products are safe and effective. The Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are responsible for overseeing aspects of a system of independent institutional review boards (IRB). IRBs review and monitor human subjects research, with the intended purpose of protecting the rights and welfare of the research subjects.

GAO investigated three key aspects of the IRB system: (1) the process for establishing an IRB, (2) the process through which researchers wishing to apply for federal funding assure HHS their human subjects research activities follow ethical principles and federal regulations, and (3) the process that medical research companies follow to get approval for conducting research on human subjects.

GAO investigated these three aspects of the IRB system by creating two fictitious companies (one IRB and one medical device company), phony company officials, counterfeit documents, and a fictitious medical device.

To view the full product, including the scope and methodology, click on [GAO-09-448T](#). For more information, contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov.

HUMAN SUBJECTS RESEARCH

Undercover Tests Show the Institutional Review Board System Is Vulnerable to Unethical Manipulation

What GAO Found

The IRB system is vulnerable to unethical manipulation, which elevates the risk that experimental products are approved for human subject tests without full and appropriate review. GAO investigators created fictitious companies, used counterfeit documents, and invented a fictitious medical device to investigate three key aspects of the IRB system. These are the results:

Establishing an IRB. GAO created a Web site for a bogus IRB and advertised the bogus IRB's services in newspapers and online. A real medical research company contacted the bogus IRB to get approval to join ongoing human trials involving invasive surgery—even though GAO's investigators had no medical expertise whatsoever. Since the transaction involved privately funded human subjects research and did not involve any FDA-regulated drugs or devices, GAO's bogus IRB could have authorized this testing to begin without needing to register with any federal agency.

Obtaining an HHS-approved assurance. GAO also registered its bogus IRB with HHS, and used this registration to apply for an HHS-approved assurance for GAO's fictitious medical device company. An assurance is a statement by researchers to HHS that their human subjects research will follow ethical principles and federal regulations, which is required before researchers can receive federal funding for the research. On its assurance application, GAO designated its bogus IRB as the IRB that would review the research covered by the assurance. Even though the entire process was done online or by fax—without any human interaction—HHS approved the assurance for GAO's fictitious device company. With an HHS-approved assurance, GAO's device company could have applied for federal funding for human subjects research.

Obtaining IRB approval for human testing. GAO succeeded in getting approval from an actual IRB to test a fictitious medical device on human subjects. GAO's fictitious device had fake specifications and matched several examples of "significant risk" devices from FDA guidance. The IRB did not verify the information submitted by GAO, which included false information that FDA had already cleared GAO's device for marketing. Although records from this IRB indicated that it believed GAO's bogus device was "probably very safe," two other IRBs that rejected GAO's protocol cited safety concerns with GAO's device. No human interaction with these IRBs was necessary as the entire process was done through e-mail or fax. GAO's bogus IRB mentioned above also could have approved the fictitious protocol, which shows the potential for unethical manipulation in the IRB system.

GAO briefed HHS officials on the results of its investigation. The director of OHRP stated that, when reviewing assurance applications, HHS does not consider whether IRBs listed on the applications are adequate—even though HHS is required to do so by law. In addition, HHS officials stated that the department does not review assurance applications to determine whether the information submitted by applicants is factual.