Human Subject Protection:
FDA's Role in a System of Safeguards

Without studies of new drugs, biologics and devices in clinical trials, the development of new health-care products would plummet; and without knowledgeable and voluntary participants, clinical trials would come to a halt. Both for the health and safety of individual study participants and for the integrity of the product development process, protection of human subjects in product studies is highly important.

The Food and Drug Administration is one of four parties involved in the oversight of clinical research into FDA-regulated products, providing a system that protects the rights and welfare of study subjects. The parties include:

- The **product sponsor** monitors the overall conduct of the study.
- An **Institutional Review Board** (IRB) composed of physicians, scientists, and other knowledgeable members, among other functions, reviews research to assure the protection of human participants.
- The **clinical investigator** and study staff make sure that participants understand what the study will entail, including the potential risks of the experiment, and make sure that the study protocol is followed properly.
- The **FDA,** whose product reviews depend on the validity of clinical trial data, oversees the entire system.

The FDA's efforts to protect human subjects generally emphasize education, training, and outreach for clinical investigators and IRBs. In addition, the FDA conducts about 1,000 trial-associated inspections a year, several hundred of which involve extensive interviews with IRB administrators and examination of their records, procedures, and responsiveness to participants' concerns. Inspections and audits carried out under this bioresearch monitoring program cover all of the parties involved in clinical trials, including clinical investigators, IRBs, product sponsors, study monitors, and contract research organizations.

In recent years, oversight of human subject protection has become more essential than ever because of developments such as an increase in the number of clinical trials, proliferation of multi-site clinical trials, emergence of new technologies such as gene therapy, and an increase in clinical studies involving "vulnerable" populations, such as children.

The FDA is working with the Office for Human Research Protections of the Department of Health and Human Services to improve the system of human subject protection. As part of this effort, the department is developing better guidance to enhance the informed consent process and is clarifying how to manage financial interests of investigators and others involved in the clinical trials to help ensure that research is conducted properly and its results are analyzed and presented objectively.

For more information, call the FDA's Office for Good Clinical Practice, 301-827-4000, or visit the FDA Web site at *www.fda.gov/oc/gcp/*.

Emphasis on Good Clinical Practices

The FDA requires that the biomedical research it regulates conforms to regulations for Good Clinical Practice (GCP), which set standards for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Compliance with GCP ensures that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected. The FDA's focal point for GCP issues arising in human research trials regulated by the agency is the Office for Good Clinical Practice (OGCP), which is part of the FDA Commissioner's office. OGCP functions include coordination of the FDA's policies on clinical studies and human subject protection. The office also coordinates the FDA's bioresearch monitoring program, administers the agency's Human Subject Protection/Good Clinical Practice Steering Committee and plans and conducts outreach programs and training.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Office of Public Affairs
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