

The Food and Drug Administration (FDA)'s clinical trials guidelines were established in the 1970s to oversee experimental testing for pharmaceutical products, treatments and procedures. The FDA uses as principals of these guidelines Good Clinical Practices (GCP) and Human Subject Protection (HSP.) The federal agency has two internal review committees, one focusing on the scientific aspect and the other on the well-being of the human subjects. The agency also follows federal law under the Federal Policy for the Protection of Human Research Subjects .

The FDA has a Bioresearch Monitoring (BIMO) program knowledgeable in medical science that provides in-person, on-site reviews and inspections for all studies, both medical and otherwise, for products and practices that are being submitted for consideration by the FDA.

The FDA appoints Institutional Review Boards (IRBs) that review clinical trials. The IRBs have many regulations concerning their written procedures, especially in the case of incidents posing risk to the human subjects, noncompliance. The official website explains that the, "primary mechanism for ensuring the adequacy of informed consent and other aspects of human subjects protection is IRB review," and that the IRB must approve the terms and conditions of the clinical trial before subject involvement. This is also the explanation for the litany of oversight measures required of the IRBs.

Each IRB must have a minimum of five members from various walks of life. One of them must be from a scientific background, another not from a scientific background and one not affiliated with any participating institutions. An INS must be from a culturally and racially diverse background and spend some time reviewing the procedures with an emphasis on how it might affect "a vulnerable category of subjects," including minors, the disabled, pregnant women and prisoners.

The participation of minors must present minimal risk and only when "adequate provisions are made for soliciting the assent" of the children and their guardians.

The FDA requires all clinical trial participant agreements to be kept on file along with signatures of release from the trial subjects, which may be considered equally binding in paper or electronic form. Consent forms must include language of informed consent that explains the function of the research, the time commitment, information about confidentiality if any, compensation claims and the statement that participation is voluntary. Forms must also include a procedural explanation including the identification of experimental procedures, a warning about any risks or discomforts as well as benefits, the admission of possible alternative treatments and recommendations should injury or illness induce as a result of the study.

Informed consent regulations also stipulate that language specifically include the fact that the participants' information will be entered into the National Institutes of Health/National Library of Medicine (NIH/NLM)'s clinical trial registry databank. Inclusion in the databank is itself mandated.

The agency has a host of rules concerning what types of clinical trial results may be used in the advertising and marketing of pharmaceuticals and treatments.