FDA Finalizes Informed Consent Guidance for Clinical Investigations

9/30/2023

On August 15, 2023, the U.S. Food and Drug Administration (FDA) issued final guidance entitled "Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors" which supersedes its prior guidance issued in September 1998 and finalizes its draft guidance from July 2014.

The guidance provides general guidance as well as a series of frequently asked questions regarding the FDA's informed consent requirements for agency- regulated clinical investigations of drugs and medical devices. The updated guidance specifies the roles and responsibilities of Institutional Review Boards (IRBs), clinical investigators, and sponsors in ensuring proper informed consent. It also covers various other topics, including the content of consent forms, the prevention of coercion, managing new information during research, and the FDA's review of criteria and issues involving diverse populations and electronic consent.

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