

New Draft Guidance for Postmarketing Studies and Clinical Trials

The draft guidance provides information for the new section 505(o) of the Food, Drug, and Cosmetic Act (the Act). This guidance provides additional information about the requirements for postmarketing studies and clinical trials and the types of studies that will generally be required under the new legislation.

1. FDA may require applicants to conduct studies and clinical trials at the time of approval or after approval if FDA becomes aware of new safety information.
2. Applicants are required to report on the status of studies and clinical trials.

Under this draft guidance, the FDA has provided a list of conditions that must be met where applicants are required to conduct a post marketing study or studies or clinical trial(s). When these conditions are met, the FDA intends to require the study or clinical trial as a postmarketing requirement (PMR). Although most studies or trials might be broadly construed to evaluate safety, the FDA does not intend to consider all postmarketing studies and clinical trials as PMRs.

FDA has also provided an inconclusive list of studies and clinical trials that would generally apply to the new guidance and those types of studies or clinical trials that would not meet the requirements for PMRs.

For more information regarding the guidance, please visit:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf>

FDA Shortens Time it Takes To Debar Investigators

The FDA will employ additional resources to assist in the review of cases which may result in clinical investigator debarment. The outcome of these investigations will be posted on the FDA's website titled "Inspections, Compliance, Enforcement and Criminal Investigations." Because IRBs are required to confirm the credentials of the Investigators that are participating in the research for which it has jurisdiction, this information will prove to be valuable.

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Harrison IRB Q&A – Investigator's Brochure

Question: Must an investigator's brochure be included in the documentation when an IRB reviews an investigational drug study?

Answer: For studies conducted under an investigational new drug application, an investigator's brochure is usually required by FDA [21 CFR 312.23(a)(5) and 312.55]. Even though 21 CFR Part 56 does not mention the investigator's brochure by name, much of the information contained in the document is clearly required to be reviewed by the IRB. The regulations do outline the criteria for IRB approval of research 21 CFR 56.111(a)(1) requires the IRB to assure that risks to the subjects are minimized. 21 CFR 56.111(a)(2) requires the IRB to assure that the risks to subjects are reasonable in relation to the anticipated benefits. The risks cannot be adequately evaluated with out review of the results of previous animal and human studies, as summarized in the investigator's brochure. It is common that the investigator's brochure is submitted to the IRB, and the IRB may establish written procedures which require its submission. Investigator's Brochures may be part of the investigational plan that the IRB reviews when receiving medical device studies. FDA Information Sheets: Frequently Asked Questions

FDA Requires IRB Registration

On January 15, 2009, the final rule was published regarding IRB Registration. IRBs were required to register with the FDA by September 14, 2009. Harrison IRB has registered to conduct both FDA and OHRP studies. Our registration number is IRB00007126.