

What's New in GCP? FDA Proposes Revising Informed Consent Regulation to Include Information on Trial Registration

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The FDA proposed revising 21 C.F.R. §50.25 to add notification in informed consent documents that information on the trial has or will be submitted for inclusion in ClinicalTrials.gov's trial registry.

In a Dec. 29 Federal Register notice (74 Fed. Reg. 68750), the FDA said the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated that the agency update its informed consent regulations. The proposed regulations require consent documents and processes for trials covered under the law to include a statement regarding the inclusion of trial information in the registry databank.

The agency noted that FDAAA did not amend the statutory provision concerning investigational device exemptions; however, "Title VIII of FDAAA generally applies to both drug and device clinical investigations. Human subject protection applies to all clinical trials, regardless of the type of treatment being studied, and FDA can find no justification for a scheme that would result in device trials having different or lesser requirements for human subject protection and informed consent."

The agency added that subject knowledge of the registry and information about the trial that may be included in the registry "could affect an individual's decision to participate in a clinical trial; as such, knowledge of this information is equally important for potential participants in clinical device trials as it is for potential participants in clinical drug trials."

In addition, requiring only drug trials to include registry information in consent documents "could result in confusion among those who conduct clinical trials over what is required in informed consent documents and processes."

The regulation amendment includes a specific statement that must be included in informed consent documents. It states:

"Information, that does not include personally identifiable information, concerning this clinical trial has been or will be submitted, at the appropriate and required time, to the government-operated clinical trial registry databank, which contains registration, results and other information about registered clinical trials. This databank can be accessed by you and the general public at www.ClinicalTrials.gov. Federal law requires clinical trial information for certain clinical trials to be submitted to the databank."

The FDA said that a "specific statement will help ensure that consistent information about the clinical trial databank is provided to clinical trial participants." The agency noted that investigators and institutional review boards can include other information about the registry; however, the required statement "must be used to satisfy the requirements of this rule, if finalized."

Benefits of Registry Notification Noted

The notice said there are “several benefits” to adding registry information to the required informed consent elements.

First, it will increase public awareness of the registry and increase trial transparency. “In particular, it would enable individuals to access more detailed information about trials relevant to their medical conditions of interest.” It also will “foster individuals’ ability to make a fully informed decision about participating in a clinical trial,” the notice said.

“Second, it would provide greater accountability and responsibility of investigators for outcomes and adverse events and would improve transparency of all clinical trial outcomes information. Informing clinical trial participants and potential patients about the databank and directing them to www.ClinicalTrials.gov would become part of a system of checks and balances for the research community and a means of ensuring that researchers, investigators and manufacturers or sponsors comply with their legal requirements under FDAAA,” the agency said.

Third, it will “increase public confidence in the validity of the research process. With the knowledge that the information generated by the clinical investigation is likely to be made public, and thus subject to additional scrutiny, participants can anticipate that the trial ‘results’ could have more impact on other medical research and analysis.”

Fourth, it will “give sponsors, physicians and patients access to more information and thus enable them to make more educated treatment decisions.”

The agency added that the statement will “lead to better promotion and protection of public health, help foster innovation to further the scientific process, and reduce duplicative research efforts.”

Under the regulations, the requirement will apply to “controlled clinical investigations other than Phase 1 clinical investigations of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351” of FDAAA.

The regulation applies to device trials that “are a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.”

To Find Out More

The Federal Register notice is available at <http://edocket.access.gpo.gov/2009/pdf/E9-30751.pdf>.

The proposed change to the elements of informed consent will be open for public comment until March 1. Submit electronic comments identified by Docket No. FDA–2009–N–0592 and/or RIN number 0910–AG32 to www.regulations.gov.

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