

What's New in GCP?

OIG Wants More FDA Oversight of Investigators

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The Department of Health and Human Services Office of Inspector General (OIG) continues to chide the FDA for not strengthening the agency's oversight of clinical investigators.

The OIG's 2009 Compendium of Unimplemented Recommendations, which was issued May 29, noted that, although the FDA has made some progress, "we continue to recommend that FDA publish guidance for justifying disqualifying clinical investigators."

The OIG noted that, since its last report in 2007, the FDA had set up several working groups to examine the process of disqualification of clinical investigators and to identify best practices for enhanced communications between centers that conduct the studies and field investigations in FDA's Office of Regulatory Affairs. In addition, the agency has developed draft guidance for sponsors, clinical investigators, and institutional review boards (IRBs) "to provide advice on a range of topics such as information sharing, data retention, and informed consent."

The new OIG report also again chided the FDA regarding its postmarketing oversight of drugs. It noted its June 2006 report that found "vulnerabilities that raised concerns that FDA was not able to readily determine whether or how promptly postmarketing study commitments were progressing toward completion."

The OIG noted that, since the 2006 report, the Agency has issued guidance to describe in greater detail the content, form and timing of postmarketing reports, and enhanced its database to include new functions and other improvements. In addition, the FDA Amendment Act of 2007 required the FDA to review the entire backlog of postmarketing safety commitments annually to determine which commitments require revision or should be eliminated and to report the determinations to Congress.

"Although we acknowledge FDA's efforts, we continue to recommend that FDA improve its management information system for monitoring postmarketing study commitments and ensure that annual status reports are being validated," the OIG said.

The OIG's 2007 concerns regarding the effectiveness of IRBs due to inadequate review time, unavailability of subject matter expertise, inadequate continuing reviews of approved research, conflicts that threaten IRB independence, and inadequate training for investigators and board members have been removed in the most recent report.

However, the OIG added concerns about compliance with federal financial conflict-of-interest regulations. In a January 2008 report, the OIG noted that the National Institutes of Health (NIH) and its Office of Extramural Research (OER) "could not provide an accurate count of the financial conflict-of-interest reports they received from grantees because the regulations did not explicitly require reporting of the nature of the conflicts or other details." In addition, grants officials did not know what types of conflicts existed and had little information on which to follow up, and NIH's "primary method of oversight was to rely on grantees' assurances that financial conflict-of-interest regulations were being followed."

The OIG recommended NIH increase its oversight of grantee institutions to ensure compliance with federal financial conflict-of-interest regulations; require grantee institutions

to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced or eliminated, and amend the current regulation to require the submission of such details; and require institutes to forward to OER all financial conflict-of-interest reports they receive from grantee institutions and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions.

The OIG noted NIH concurred with two of the recommendations but not with requiring grantee institutions to provide additional details regarding financial conflicts. The NIH contended the grantee institutions were responsible for identifying and managing financial conflicts of interest. "We continue to recommend that NIH collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions; work to amend the current regulation; and, in the interim, use its authority [under 42 C.F.R. §50.604(g)(3)] to request details regarding the nature and management of financial conflicts of interest at grantee institutions."

To Find Out More

The OIG report is available at
<http://www.oig.hhs.gov/publications/docs/compendium/compendium2009.pdf>.

Other Recent GCP Developments in the Guide to Good Clinical Practice

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VA Responds to IG Informed Consent Concerns

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