JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 9, No. 9, September 2013 "Happy Trials to You"

What's New in GCP?
HHS Finalizes Rule Exempting Misconduct Records from Privacy Act

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After withdrawing direct final rules on exempting FDA and National Institutes of Health research misconduct records from certain requirements of the Privacy Act, the Department of Health and Human Services published final rules, effective July 31, under the standard notice and comment rulemaking process July 1.

HHS "believes the exemptions at issue are necessary to fulfill the agency's responsibilities for addressing research misconduct. The exemptions are essential in order for [FDA and NIH] to protect the confidentiality of sources who provide information relevant to a research misconduct proceeding and to guard against the premature disclosure of research misconduct records that might obstruct or compromise proceedings. The exemptions will thereby enable [FDA and NIH] to maintain the integrity and effectiveness of research misconduct proceedings.

"Failure to adopt the exemptions would jeopardize the integrity and effectiveness of [FDA's and NIH's] research misconduct proceedings," the announcements said, noting FDA's and NIH's new systems of records are modeled after the system maintained by HHS' Office of Research Integrity, which "has exempted these records under subsections (k)(2) and (k)(5) of the Privacy Act from the notification, access, accounting and amendment provisions of the Privacy Act, to ensure that these records will not be disclosed inappropriately." HHS "believes that exempting the new [FDA and NIH systems] from the same Privacy Act provisions is essential to ensure that material in [the] files related to research misconduct proceedings is not disclosed inappropriately."

The final rules exempt the agencies from the Privacy Act requirements to provide:

- Accounting of disclosures during the pendency of a research misconduct proceeding. "Release of an accounting of disclosures to an individual who is the subject of a pending research misconduct assessment, inquiry or investigation could prematurely reveal the nature and scope of the assessment, inquiry or investigation and could result in the altering or destruction of evidence, improper influencing of witnesses, and other evasive actions that could impede or compromise the proceeding," HHS said.
- Access both during and after a research misconduct proceeding, to avoid revealing the identity of any source who was expressly promised confidentiality. "Only material that would reveal a confidential source will be exempt from access. Protecting the identity of a source is necessary when the source is unwilling to report possible research misconduct because of fear of retaliation (e.g., from an employer or coworkers)."
- Amendments while one or more related research misconduct proceedings are pending. "Allowing amendment of investigative records in a pending proceeding could interfere with that proceeding. Even after that proceeding is concluded, an amendment could interfere with other pending or prospective research misconduct proceedings or could significantly delay inquiries or investigations in an attempt to resolve questions of accuracy, relevance, timeliness and completeness," HHS said.

- Notification provisions during the pendency of a research misconduct proceeding. "Notifying an individual who is the subject of an assessment, inquiry or investigation of the fact of such proceedings could prematurely reveal the nature and scope of the proceedings and result in the altering or destruction of evidence, improper influencing of witnesses, and other evasive actions that could impede or compromise the proceeding.
- Procedures for notification, access to records, amendment of records, or appeals of denials of access to records, because the procedures would serve no purpose in light of the other exemptions.

HHS noted that "to avoid the unnecessary application of the exemptions," FDA and NIH "will give case-by-case consideration to requests for notification, access and amendment" submitted to the agencies' Research Integrity Officer (System Manager) or Privacy Act coordinator (FDA) or officer (NIH). In addition, "except for information that would reveal the identity of a source who was expressly promised confidentiality, the access exemption will not prohibit [HHS] from granting respondents' access requests consistent with the PHS Policies on Research Misconduct (42 C.F.R. Part 93), including in those cases in which a finding of research misconduct has become final and an administrative action has been imposed. The request submission process was described in the agencies' notices for the new systems.

To Find Out More

The notice (78 Fed. Reg. 39184) of the FDA final rule is available at www.gpo.gov/fdsys/pkg/FR-2013-07-01/pdf/2013-15599.pdf.

The notice (78 Fed. Reg. 39186) of the NIH final rule is available at www.gpo.gov/fdsys/pkg/FR-2013-07-01/pdf/2013-15596.pdf.

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