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Pharmaceutical and Biotechnology Alert

Last week, the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS) issued joint draft guidance on responsibilities for preparing and maintaining written policies and procedures for Institutional Review Boards (IRBs). The agencies, both responsible for issuing and enforcing federal regulations designed to protect human subjects in research, have been working together to harmonize federal regulatory requirements and guidance in this area. The draft guidance entitled "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs" (the Draft Guidance) is designed to assist IRBs and institutions responsible for the review and oversight of human research protections under both FDA (21 CFR Parts 50 and 56) and HHS regulations (45 CFR Part 46).

FDA and HHS regulations generally require IRB review and approval of regulated clinical research to safeguard the protection of human subjects. The regulations require that IRBs draft and follow written procedures for certain activities listed under 21 CFR 56.108 and 45 CFR 46.103. Written procedures must cover, for example: conducting review of research, reporting findings/actions to the investigator and institution, determining the timing of review, and ensuring that (1) changes in research are not initiated without IRB approval except in limited circumstances; and (2) certain issues are promptly reported to the IRB, FDA, OHRP, and other appropriate institutions. However, the regulations do not describe in detail the content of IRB written procedures.

Through this Draft Guidance, the agencies have created an "IRB Written Procedures Checklist" that supports FDA and HHS requirements and accounts for variation among IRBs and research institutions. The 59-section checklist provides detail designed to ensure that IRB members and administrative staff understand their duties to protect the rights and welfare of subjects. The checklist identifies the agencies’ regulatory requirements and recommended written procedures to ensure that IRB functions and operations are adequately documented. Compared to the regulations, the checklist provides both a more comprehensive framework and a detailed set of recommended operational procedures for IRBs. For example, the Draft Guidance identifies the following written procedures for conducting a review at a meeting of the convened IRB:

This latest effort to harmonize federal regulatory requirements and provide guidance to the regulated industry follows on the heels of the National Institutes of Health's (NIH) final policy issued in June 2016, entitled “Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research” (Single IRB Policy). The Single IRB Policy is intended to streamline IRB oversight by requiring a single IRB to review research conducted at all locations of multi-site, NIH-funded clinical studies. With an ever increasing number of federally-funded clinical study protocols conducted at multiple locations, the purpose of the single IRB requirement is to eliminate duplicative IRB review, although some institutions remain apprehensive of the single IRB concept and the appropriate allocation of responsibility for ancillary reviews (e.g., biosafety review), local context review, regulatory reporting, liability, and cost. Prior to the effective date of the policy in May 2017, NIH intends to release guidance documents and resources providing details to assist IRBs and institutions in adjusting to the new policy.

FDA and OHRP's new Draft Guidance along with NIH's Single IRB Policy come at a time when many in the research community await imminent changes to the Common Rule. Nevertheless, these recent federal pronouncements provide needed guidance and have been expected for some time. During FDA's Bioresearch Monitoring (BIMO) and OHRP's compliance audits, investigators routinely evaluate an IRB's written policies and procedures to determine if the IRB is operating in compliance with current regulatory and statutory requirements. IRB administrators, IRB chairpersons, and those responsible for an institution's human research protection program should evaluate their written policies and procedures in light of the Draft Guidance and the Single IRB Policy. Recently we have been involved in several institutional reassessments of IRB policies and procedures, and the new federal guidance will figure in these assessments going forward. Written comments in response to the FDA and OHRP Draft Guidance must be submitted to the IRB (e.g., protocol, informed consent form, investigator brochure, recruitment materials, HHS-approved protocol and sample informed consent form).

- Timelines for receipt of submissions, scheduling IRB review, and document distribution to IRB members.
- The type of reviewer system utilized by the IRB at a convened meeting (e.g., primary reviewer(s)).
- A list of documents routinely distributed to all IRB members and a list of documents distributed to any specific IRB members (e.g., primary reviewer(s)).
- The range of possible actions that can be taken by the IRB (e.g., approve, require modifications to secure approval, disapprove, suspend or terminate approval of a study).
submitted to FDA by October 3, 2016.

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