AMERICAN HEALTH LAWYERS ASSOCIATION

PRACTICE GROUP email alert

To: Life Sciences *and* Teaching Hospitals and Academic Medical Centers Practice Group Members

From: Life Sciences *and* Teaching Hospitals and Academic Medical Centers Practice Group Leaderships

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**FDA Issues Draft Guidance to IRBs Regarding Their Responsibilities to Evaluate Clinical Investigators and Research Sites and the Determination of the Need for INDs/IDEs**

By Maureen Bennett and Karl Nobert*

On November 20, the U.S. Food and Drug Administration (FDA) published in the *Federal Register* a Draft Guidance that provides institutional review boards (IRBs) with further instruction regarding their responsibilities to evaluate the qualifications of clinical investigators and the adequacy of research sites used in connection with clinical research. We focus on these instructions in this alert.

The Draft Guidance also provides instruction regarding an IRB's role in assessing the need for an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application.

FDA is accepting comments until January 22, 2013, on this Draft Guidance entitled, "IRB Responsibilities for Reviewing Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed."

***Cooperation Among Agencies***

The Draft Guidance was developed by FDA in consultation with the U.S. Department of Health & Human Services Office for Human Research Protections as part of the agencies' ongoing efforts to harmonize human subject protection requirements.

***Qualification of Investigators***

The Draft Guidance notes that although clinical trial sponsors have the responsibility under FDA regulations to select clinical investigators who are "qualified by training and experience as appropriate experts" to investigate the test article or investigational new drug (citing 21 CFR 312.53(a) and 21 CFR 812.43(a)), IRBs also have a role in reviewing investigator qualifications. This duty is stated to be derived from an IRB's general obligations to ascertain the acceptability of the proposed research and to determine that the proposed research satisfies the criteria for approval, including that risks to subjects are minimized and reasonable in relation to anticipated benefits, if any, to subjects (citing 21 CFR 56.107(a)).

"In order to fulfill these responsibilities, the IRB needs information about

the qualifications of the investigator(s) to supervise the proposed research." (Draft Guidance at page 2.)

FDA suggests levels of due diligence that may be appropriate for an IRB to evaluate an investigator. It suggests that to the extent the IRB has prior experience with the investigator or the institution, this may allow for the IRB to sufficiently determine the investigator's qualifications. In other cases, the IRB might rely on a statement from an administrator of the institution or, if the investigator is a university faculty member, the IRB might rely on a statement from the chair of the investigator's department as to the investigator's qualifications.

If the IRB has no previous knowledge or experience with the investigator or institution, FDA suggests that more substantial due diligence is required, including reviewing the curriculum vitae of the investigator and that of any sub-investigator or study staff and verifying professional publications and medical licensure. Further, the IRB may also need to analyze an investigator's particular qualifications regarding a proposed study, especially if it poses higher risks or involves vulnerable subjects or novel technologies. FDA suggests that the IRB be particularly attuned to the qualifications of sponsor-investigators or where the study poses special risks or is outside the investigator's area of expertise.

*Comment*

It is important that IRBs develop specific guidelines for assessing and documenting the qualifications of investigators, including establishing criteria for determining those investigators and institutions that are already known to the IRB. In this regard, IRBs should consider whether corresponding principles regarding independence and conflict of interest may militate in favor of confirming the credentials of an investigator that is already "known," especially if the IRB has never documented its initial assessment of the investigator's qualifications. Also, given the potential increase in administrative duties, IRBs might consider the extent to which sponsors may have received from the investigator his/her medical licensure and specific qualifications to perform the study protocol. The IRB's procedures should also include checking applicable FDA investigator disqualification or enforcement websites.

***Adequacy of Research Sites***

FDA cites the above-mentioned general IRB obligations to ensure the acceptability of the proposed research in advising that the IRB also must assess the sufficiency of the proposed clinical research site. Similar to its observations regarding the assessment of clinical investigators, FDA suggests that the due diligence may be fairly straightforward to the extent the research site is known to the IRB or is one with which it has an affiliate relationship.

In other cases, a more detailed assessment is required. FDA suggests that the IRB should be prepared to assess the adequacy of a facility's staff and equipment, including the availability of emergency or specialized care. The IRB might rely on a statement of an appropriate member of the research site or may ask for a presentation from the investigator as to the research site and its staffing and resources.

*Comment*

It is important that IRBs develop specific guidelines for assessing and

documenting the adequacy of research sites, including establishing criteria for assessing a particular research site's equipment, facilities, and staffing to accommodate specialized research. In that regard, the assessment of a research site should be made in consideration of the specifics of the clinical trial protocol under review.

**We would like to thank Maureen Bennett, Esquire, and Karl M. Nobert, Esquire (Squire Sanders LLP, Boston, MA, and Washington, DC), for providing this email alert.*

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