

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Direct Accountability for External IRBs? The Office for Human Research Protections Seeks Your Comments

March 26, 2009

On March 5, 2009, the Office for Human Research Protections ("OHRP")¹ published a request for information and comments regarding whether it should hold Institutional Review Boards, and the institutions or organizations operating the Institutional Review Boards (collectively, "IRBs"), directly accountable for meeting certain regulatory requirements related to the protection of human subjects.² Currently, only the institutions actually conducting the research are directly accountable to the OHRP, even in circumstances where the regulatory violation is directly related to the responsibilities performed by an external IRB.

IRBs are the administrative bodies that are responsible for conducting initial and continuing review of research that is conducted or supported by the Department of Health and Human Services (HHS) in order to ensure the protection of the rights and welfare of human research subjects. Each IRB has the authority to approve, require modification of, or disapprove all research activities supported by HHS.

Institutions engaged in research involving human subjects may use internal or external IRBs to review research they intend to conduct. The flexibility to choose an external IRB was intended to be a means of reducing administrative burdens of duplicative IRB review and, for those institutions that would choose not to establish an internal IRB, the time and personnel costs associated with operating an IRB. For example, two or more institutions engaged in the same multi-center research project could designate the same IRB, rather than each institution's internal IRB reviewing the same study.

Currently, most institutions opt to have each research study reviewed by their own internal IRB rather than designating an external IRB. The OHRP has found that institutions conducting HHS-supported human subject research are not taking advantage of the ability to use external IRBs in large part because of OHRP's practice of holding the institution responsible for an external IRB's noncompliance with OHRP regulations rather than holding the external IRB itself responsible.

¹ The OHRP is the regulatory agency within the Department of Health and Human Services ("HHS") responsible for regulating research involving human subjects conducted or supported by HHS.

² 74 Fed. Reg. 9578 et seq. (Mar. 5, 2009).

The OHRP recognizes that its regulatory enforcement mechanism was created at a time when single-site research studies were more common and that this method may no longer be the most efficient means of enforcement given the increasing use of multi-site studies and non-traditional research settings (e.g., community hospitals and medical clinics). As a result, the OHRP is considering proposing rules to broaden its enforcement capabilities as a means of encouraging reliance on IRBs operated by external institutions or organizations. By doing so, the OHRP believes institutions engaged in human subject research may be able to avoid the current inefficiencies of duplicative IRB review, or the expense of operating an IRB, without diminishing protections to human subjects.

In particular, OHRP is considering expanding its enforcement authority to cover IRBs. This enforcement authority would allow OHRP to hold IRBs directly accountable for ensuring that human subject research meets certain regulatory requirements that traditionally have only been enforced against the research institution. In these situations, the OHRP indicates that it "would generally expect to enforce compliance with [regulatory requirements] directly with the external IRB, and not with the [research] institution."³ The OHRP envisions exercising this enforcement capability only when the IRB at issue is external to the institution engaged in the research and only when such IRB has been appropriately designated as its external IRB by the institution engaged in the research. For internal IRBs, OHRP expects to continue enforcing compliance through the research institution.

OHRP has made an initial attempt at grouping its regulatory requirements into the following three categories: (1) responsibilities that may be unique to IRBs (and therefore for which OHRP may hold an external IRB directly accountable); (2) responsibilities that may be unique to institutions engaged in human subjects research; and (3) responsibilities that may be fulfilled by either IRBs or institutions engaged in human subjects research. The list of regulatory requirements OHRP has initially grouped into each of these categories is available at 74 Fed. Reg. at 9581.

OHRP is seeking information and comment regarding whether it should pursue notice and comment rulemaking to hold IRBs directly accountable for meeting certain regulatory requirements and is also seeking comment regarding several specific questions related thereto, including the initial categorization of responsibilities. The full list of questions is available at 74 Fed. Reg. at 9582. Comments are due by June 3, 2009 and may be submitted by email, fax, or mail.⁴ If you have any questions regarding this Health Law Update, please contact any of the attorneys in our Healthcare Practice Group listed below.

³ 74 Fed. Reg. at 9580 (emphasis supplied).

⁴ Comments sent by email should be directed to IRBaccountability@hhs.gov (include "IRB Accountability RFI" in the subject line), by fax to 301.402.2071, and by mail to Julie Kaneshiro, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

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