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Health Law Alert: OHRP Publishes New Registration Requirements for IRBs

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On January 15, 2009, the Office for Human Research Protections (OHRP) published new registration requirements for institutional review boards (IRBs)[1] and expanded the amount of information to be collected from registering IRBs. The requirements apply to IRBs designated under an assurance of compliance for federal-wide use by OHRP and engaged in human-subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). Under the new rules, registration will be effective for three years. This final rule comes after OHRP's Notice of Proposed Rulemaking, which was published on July 6, 2004.[2]

Any existing or newly formed IRB that fails to register with HHS will not be eligible for Federalwide Assurance (also known as "FWA") designation, which allows federal departments and agencies to deem the IRB in compliance with the HHS human subjects regulations.

OHRP's goal is to use the new data it will be collecting from registered IRBs to provide better and more tailored information and support to IRBs. By way of background, OHRP implemented a registration system for IRBs in December 2000 in order to:

- identify more precisely those IRBs reviewing research conducted or supported by HHS;
- keep an accurate up-to-date list of IRBs;
- send educational information and other information to IRBs; and
- identify IRBs that are subject to HHS regulations for monitoring and oversight purposes.

The existing IRB registration rules require institutions engaged in human subjects research to file an "assurance of compliance" that includes information about the institution's designated IRBs, the IRB members identified by name, and the IRB members' academic and employment experience.

Under the final rule's additional registration requirements, the IRB must provide:

- various IRB staffing and contact information;
- the approximate numbers of all active protocols undergoing initial, expedited, or continuing review; and
- the approximate number of full-time-equivalent positions devoted to the IRB's administrative activities.[3]

In addition, organizations must report their decision to disband a registered IRB within thirty days of permanent cessation of the IRB's review of research supported or conducted by HHS.

The effective date of the new rule is July 14, 2009. OHRP has protracted the effective day to allow time to update the electronic system in accordance with the final rule. IRBs must complete registration within 60 days of the effective date, or by September 14, 2009. IRBs that are currently registered with OHRP must submit all information required under the rule by the three-year expiration date previously assigned by OHRP or within 90 days of any changes relating to the IRB chairperson or the contact person who provided the IRB registration information to HHS.

IRBs should note that the final rule was simultaneously published with the Food and Drug Administration's IRB registration requirements. These requirements are compatible with one another and will allow HHS to operate a single IRB registration system.

Endnotes

[1] *See* 74 Fed. Reg. 2399 (2009), *available at* http://edocket.access.gpo.gov/2009/pdf/E9-588.pdf. *See also* 45 C.F.R. § 46.501-505. The regulations can be found under the newly added Subpart E of the human subjects regulations. Only institutions that do not have online access may register in writing.

[2] *See* 69 Fed. Reg. 40584 (2004), *available at* http://edocket.access.gpo.gov/2004/pdf/04-14679.pdf.

[3] Active protocols are defined as reviews that occurred or began within the preceding 12 months.

For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

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