FDA and Office for Human Research Protections Issue Companion Regulations Requiring IRB Registration

On January 15, 2009, the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) issued companion regulations mandating new or expanded registration of institutional review boards (IRBs). These regulations respond to criticism that federal oversight of IRBs should be strengthened and are intended to enable FDA and OHRP to compile a comprehensive list of IRBs, send educational and other information to IRBs, and enhance monitoring and inspection of IRBs.

Under the new rule, FDA now requires an IRB to register prior to review of clinical investigations: (1) regulated by the FDA under its Investigational New Drug or Investigational Device Exemption regulations; or (2) intended to support a research or marketing permit application for FDA-regulated products. OHRP expands existing registration requirements for IRBs used by institutions to oversee research funded by the Department of Health and Human Services.

FDA and OHRP have coordinated their IRB registration rules to be substantially consistent with each other, and a joint IRB registration Web site will be used by both agencies. When registering, IRBs must provide the following information:

- contact information for the organization operating the IRB, the senior officer of the organization responsible for overseeing IRB activities, and the IRB chairperson;
- an approximate number of the IRB's active protocols;
- for IRBs subject to FDA oversight, a generic description of the types of FDA-regulated products involved in the protocols that they review (e.g., "human drugs," "medical devices"); and
- for IRBs subject to OHRP oversight, an approximate number of full-time equivalent positions allocated to IRB administrative activities.

Initial registration with all required information must be submitted by September 14, 2009. IRBs currently registered with OHRP must register prior to expiration of their registration. Registrations must be renewed periodically and updated to reflect information changes.

View the FDA regulations; view the OHRP regulations.

If you have any questions concerning the new regulations, please contact your usual Ropes & Gray advisor.