

New Regulations Mandate Institutional Review Board Registration

The Office for Human Research Protections (OHRP) has added a new subpart to Department of Health and Human Services (HHS) protection of human subjects regulations requiring Institutional Review Boards (IRB) to register with HHS. The new [regulation](#) applies to IRBs that review human subjects research conducted or supported by HHS and are designated under an assurance of compliance approved for federal-wide use by OHRP. Information to be registered includes contact information, number of active research protocols, and IRB staffing.

A [companion regulation](#) was issued by the Food and Drug Administration to require registration for IRBs reviewing clinical investigations involving FDA-regulated products. A single HHS registration system for both regulations will be accessible on the [OHRP website](#).

The two rules will become effective July 14, 2009, and initial registration must be submitted by **September 14, 2009**. Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register an IRB electronically, in which case, it must send its IRB registration information in writing to OHRP. Each IRB must renew its registration every three years. For more information, contact Irene Stith-Coleman, at 240/453-6900 or irene.stith-coleman@hhs.gov.