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# Are Local IRBs Going the Way of the Dodo? Historic Proposed Changes to the Common Rule

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The regulations governing research protections for human subjects across several federal agencies, known collectively as the Common Rule [PDF], have remained basically unchanged since their inception in the 1980s. The Department of Health and Human Services (HHS) is now revisiting the Common Rule, however, in an attempt to balance the need for additional protections for human subjects with calls for a more streamlined approval process for frustrated investigators. HHS announced its proposed changes to the Common Rule, entitled Human Subject Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators [PDF], on July 22, 2011. Along with the expansive changes proposed in its announcement, HHS posed a series of 75 questions for public comment on potential regulations.

## Why now?

After decades of institutional review boards (IRBs) working under the current Common Rule, HHS seeks to update the regulations to reflect the current research environment. For example, research is now conducted in locations other than major academic medical centers, such as community hospitals. Investigators often conduct research in multiple sites across state lines. In addition, in the 1980s when these rule were being formulated no one thought that biogenetic information collected for one study could be saved for use in future studies. Also, the widespread use of electronic data in research was not contemplated decades ago.

## Proposed Changes

HHS set out the proposed changes to the Common Rule in a table entitled Comparison of Existing Rule with Some of the Changes Being Considered. These changes would extend beyond research sponsored by government agencies to all




research funded by such agencies. HHS's proposed changes to the Common Rule cover such topics as:

- Single-IRB review for multi-state studies, rather than several local IRBs
- Updated content and processing of informed consents, including uniform templates and limitations on length and content
- Focused risk factors for IRB review
- Detailed data security protections and factors IRBs must consider in their review of research based on the Health Insurance and Accountability and Portability Act of 1996 (HIPAA)
- Established consent requirements for use of biospecimens in future studies
- Revised minimum risk, expedited review and exempt categories Contemplated efficient electronic adverse event reporting harmonizing inconsistent rules and creating real-time event reporting

It is unclear until the proposed rule is released how these changes to the Common Rule will impact the research governed by Food and Drug Administration and subject to HIPAA and its accompanying regulations. HHS will need to reconcile inconsistencies among these other laws with the release of the proposed regulation revising the Common Rule.

### The Changing Role of Local IRBs

HHS proposed the expanded use of central IRBs rather than local IRBs for multi-site studies. This change is likely to divide the research community. On one hand, a streamlined approval process addresses the concerns of investigators who worry that delays in IRB approvals mean delays in the impact of research findings. Some investigators argue that the use of local IRBs for multi-state studies means each IRB must review and approve the study before the investigator can move forward. For example, if one IRB makes changes to the informed consent document then the investigator must go back to the other IRBs for approval of the revision.




Central IRBs will streamline investigators' approval process and take work off the plates of local IRBs, who can then focus on other issues. Local IRBs take into account local issues, however, and are watch dogs for local research subjects. On the other hand, there has been some concern that the use of local IRBs can lead to IRB shopping, which can cause research subjects to receive less protection. The proposal to use central IRBs leaves some wondering: Will these central IRBs will be government run? Will they be less effective or protective?

### Submit Comments

After numerous requests for an extension, the deadline to submit comments to the advanced notice of proposed rule making has been extended to **October 26, 2011** at 5:00 pm. Comments may be submitted at www.regulations.gov using identification number HHS-OPHS-2011-0005 or by mail at Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.