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## **HHS Announces Intentions for Sweeping Changes to Regulations Governing Human Subjects Research**

On July 22, 2011, the U.S. Department of Health and Human Services announced that it is contemplating significant changes to the regulations that govern federally-supported research involving human subjects. The existing regulations, often referred to as the "Common Rule," have been in place since 1991 when they were simultaneously adopted by 14 federal government agencies and independent departments. These proposed changes would again be adopted by all such agencies, and the revision effort is being coordinated among these agencies.

Revisions to these regulations would seek to strengthen the protections for human subjects in the arenas of ethics, safety and oversight of human subjects research. The Department's announcement cites dramatic change in the categories of research being conducted, the prevalence of multisite trials, and the types of data being collected.

The Advanced Notice of Proposed Rulemaking, which sets forth the proposed revisions at a policy level and asks for specific comment on many questions related to the federal oversight of human subjects research and the conduct of such research, is available at (<http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>). A summary table of the proposed changes is available from the Office for Human Research Protections at (<http://www.hhs.gov/ohrp/humansubjects/anprmchangetable.html>).

Specifically, the Notice seeks comment on the following broad issues:

1. Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk
2. Using a single Institutional Review Board review for all domestic sites of multi-site studies
3. Updating the forms and processes used for informed consent
4. Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data

5. Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient
6. Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies
7. Providing uniform guidance on federal regulations

We will be monitoring the development of proposed regulations. If you have any questions or if we can be of assistance, please contact any member of the Honigman Health Care Department.