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**LIFE SCIENCES UPDATE****HHS Proposes Increased Human Subject Protections**

On July 22, 2011, the U.S. Department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rulemaking (ANPRM) to request comments on potential revisions to the regulatory requirements for research on human subjects. The Notice of proposed rulemaking gives interested parties an opportunity to help frame the upcoming discussion by filing comments with HHS before September 21, 2011.

This ANPRM is the first step in the process of revising human research requirements that have been in place for 20 years. Because of the critical importance of these requirements to the life sciences industry, monitoring and engagement in the HHS regulatory process is essential to ensure that industry concerns and suggestions are considered.

The standards for protection of human subjects involved in research have evolved since the Nuremberg military tribunals conducted after World War II. These standards emphasize the importance of individual autonomy and informed choice of subjects participating in human subject research. In the United States, fundamental protections of subjects were adopted following the Belmont Report recommendations of the late 1970s. Human subject protections were further revised by the Common Rule in 1991, in which more than a dozen federal departments and agencies adopted standardized protections for humans participating in research. The Common Rule requires, among other things, that investigators conducting federally funded research obtain informed consent from research subjects and that research is overseen by an institutional review board (IRB) with well-defined duties. Sponsors of clinical studies investigating products over which the U.S. Food and Drug Administration (FDA) has authority are generally required to comply with most provisions of the Common Rule, regardless of the source of the research funding.

This ANPRM is the latest development in the evolving attempt to protect human subjects in research. HHS and interested parties recognize that, with changes in technology and the methods in which human research is conducted and overseen, the current regulations may be both unduly burdensome and less protective than they should be. For example, the regulations today may require an IRB to continue to oversee a study in which the experimental part is complete and the subjects are receiving medical treatment that is both FDA-approved and meets the current standard of care. Conversely, concern that the regulations do not give adequate protection to those subjects who would like to exercise more control over the use of their genetic material may justify modifications to the Common Rule. Thus, the HHS is seeking comment on whether it should:

- Revise the current risk-based review framework to more accurately match the level of IRB review to the level of risk in a particular study.

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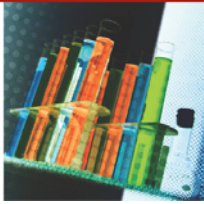
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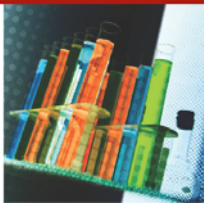


- Use a single IRB review for all domestic sites of multisite studies.
- Update the forms and processes used for informed consent.
- Establish mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.
- Implement a systematic 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.
- Extend federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from Common Rule agencies.
- Provide uniform guidance on federal regulations.

If adopted, the proposed changes will affect sponsors, investigation sites, study investigators, IRBs and, of course, human subjects participating in research. Proposed changes of special note to trial sponsors include:

- Requiring written consent from subjects for research use of biospecimens.
- Extending Common Rule regulations to apply to all studies regardless of funding source.
- Creating a single website where all adverse events from all studies would be reported.
- Adding specificity for informed consent requirements to maximize informed consent's benefit for subject protection and minimize its use by sponsors to reduce their liability risk.
- Revising the relationships between central and local IRBs.
- Revising the requirements for both expedited IRB review and exempted research.

By participating in the regulatory process, even at the early stages, life sciences companies can help shape the agenda of priorities and the regulatory framework pertaining to issues of critical importance to their operations. Life sciences companies therefore should consider informing HHS of their experiences, concerns and suggestions regarding proposed revisions to the Common Rule. To view the ANPRM, please visit <http://www.regulations.gov>; to submit comments, visit <http://www.regulations.gov> and click on "Submit a Comment."



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