



## GLOBAL LIFE SCIENCES UPDATE

### HHS Proposes Major Overhaul To Human Subjects Rules

On July 26, the Department of Health and Human Services (HHS) issued an advance notice of proposed rulemaking (ANPRM) seeking public comment on significant proposed changes to the federal requirements governing research with human subjects, known as the “Common Rule” (45 C.F.R. Part 46). The stated goal of these changes is to improve the protections of the oversight system while reducing “burdens, delays, and ambiguities for investigators and research subjects.” While the ANPRM identifies many important issues, three proposed changes in particular—related to research with biospecimens, data security, and clinical trial monitoring—could affect pharmaceutical and medical device companies and other entities that sponsor research with human subjects. Comments on the ANPRM are due by October 26, 2011.

The ANPRM proposes to require written consent for the research use of biospecimens, whether or not such specimens were initially collected for non-research purposes, and notwithstanding the removal of identifying information regarding the source of the specimens. According to the ANPRM, such consent “need not be study specific” and could include “open-ended future research.” This change would be in contrast to current HHS policies, which allow for the use of de-identified human biospecimens in research without informed consent. At the same time, the proposal is consistent with recently proposed HIPAA privacy rule changes for research authorizations.<sup>1</sup> Although the ANPRM suggests making this new Common Rule policy applicable prospectively, it could result in new requirements for study sponsors seeking to collect specimens from subjects.

The ANPRM states that participation in a research study cannot be conditioned on a participant’s agreement to “allow future open-ended research using a biospecimen.” This prohibition on conditioning participation would be similar to the current HIPAA restrictions that prohibit conditioning treatment on an individual signing an authorization for the use or disclosure of identifiable health information for future, unspecified research. The proposal leaves open whether participation may be conditioned on specified uses of biospecimens. As the prospective collection of biospecimens is increasingly viewed as necessary by FDA for the future identification of genetic factors that influence drug response, it is important that sponsors determine the potential impact of including participants who do not consent to the future use of their biospecimens.

The ANPRM also proposes to prospectively apply new data security and information protection standards to all research that involves collection, storage, analysis, or reuse of identifiable or potentially identifiable information, in place of IRB review of informational risks. The proposal would model the new data security standards on the HIPAA

<sup>1</sup> HHS Publishes Long-Awaited HITECH Proposed Rule Making Significant Modifications to the HIPAA Privacy, Security and Enforcement Rules and Takes Other Actions Related to Breach Notification and Risk Assessments  
<http://www.sidley.com/sidleyupdates/Detail.aspx?news=4562>

security rule. It also would adopt the HIPAA privacy standards for determining what constitutes individually identifiable information and de-identified health information. All biospecimens would be considered identifiable information and subject to heightened protection. For research using limited data sets or de-identified information, investigators would be strictly prohibited from attempting to re-identify the subjects of information.

Also of relevance to clinical trial sponsors, the ANPRM proposes changes to the way in which adverse events arising during clinical trials are reported, in order to “simplify and consolidate” such reporting. The changes involve the use of a “standardized, streamlined set of data elements,” the development of a web-based Federal-wide portal, and harmonization of safety reporting guidance across federal agencies. HHS also proposes to create a central data repository to store adverse event information received by all Federal agencies. According to the ANPRM, the changes would not expand the information that has to be reported.

Finally, the ANPRM proposes expanding mandatory compliance with the Common Rule for all research with human subjects at a domestic institution that receives any Federal funding from a Common Rule agency for research. Thus, even if a particular study does not involve any Federal funding or funding from a department of agency that has adopted the Common Rule, the institution would be required to follow the Common Rule for such study.

The ANPRM presents all proposed changes in the form of general discussion and questions. After considering comments received in response to the ANPRM, HHS anticipates publishing proposed regulations for formal public notice and comment. This process will afford stakeholders yet another opportunity to provide meaningful input on these significant developments.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work.

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