



GLOBAL LIFE SCIENCES: US-FDA UPDATE

Clinical Trials: New FDA/NIH Draft Guidance Would Permit Broader Patient Waiver

A September 19 draft guidance jointly issued by Food and Drug Administration (FDA) and National Institutes of Health's Office for Human Research Protections (OHRP) would allow sponsors of clinical trials to require humans subjects to waive certain legal rights, including those related to biospecimens collected for research. This departure from longstanding interpretations by both OHRP and FDA is achieved through a more narrow interpretation of federal regulations prohibiting the inclusion of "exculpatory language" in informed consent documents.

The draft guidance interprets the meaning of language contained in both the Department of Health and Human Services (HHS) and FDA regulations stating that "[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." The draft guidance construes the regulations to prohibit only language that "has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt," but to permit waivers of a subject's legal rights that would not have such effect. As a consequence, waivers of subjects' right to be compensated for biospecimens would now be permissible.

In the past, OHRP and FDA opined that informed consent documents could not characterize the use of a subject's biospecimen as a "donation," since such language implied the waiver of rights to property and therefore was exculpatory in nature. In contrast, the new draft guidance states that requiring waiver of such rights is acceptable because "it has long been common practice of investigators and sponsors not to compensate research subjects who agree to provide biospecimens," and because "OHRP and FDA are not aware of any federal or state laws or policies that suggest that research subjects would have any legal right to such compensation." Although there have been several lawsuits brought against researchers and institutions by human subjects asserting property rights in their biospecimens, none has resulted in a verdict in favor of plaintiffs.

According to the Federal Register notice, the draft guidance was developed as part of FDA's and OHRP's efforts to harmonize their requirements for human subject research and "in response to numerous questions and comments from the IRB and research communities." The [draft guidance](#) also comes as HHS [considers a broad overhaul](#) of federal human subjects protections under 45 C.F.R. Part 46, generally known as the Common Rule, that could include changes to the requirements for use of biospecimens in research.

We anticipate that there will be comments on both sides of this issue and encourage interested parties to file comments, which are due by November 7, 2011.

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