Draft Guidance Document on Exculpatory Language in Informed Consent

On September 7, 2011, the Office for Human Subject Protections (OHRP) and the Food and Drug Administration (FDA) announced in the Federal Register the availability of a joint draft document entitled, "Guidance on Exculpatory Language in Informed Consent," and are inviting public comments on that document. The joint draft document, among other things, does the following:

1. Provides guidance on the regulatory prohibition on the inclusion of exculpatory language in informed consent.

2. Includes examples of language that OHRP and FDA consider acceptable as well as examples of language that the agencies would consider exculpatory.

3. Clarifies that OHRP and FDA have concluded that language in informed consent is not exculpatory if it informs subjects that, by agreeing to allow the use of their biospecimens for research purposes, they are giving up any legal right to be compensated for the use of the biospecimens. This represents a change from OHRP's November 15, 1996 guidance on point, "Exculpatory Language in Informed Consent," which identified as "exculpatory" certain informed consent statements in which subjects gave up any rights they might have in their biospecimens.

OHRP and FDA now consider these statements to be acceptable for inclusion in informed consent, and they are restated as examples of acceptable language in the draft guidance. Thus, for example, it would now be acceptable to include language in a consent form such as "I give up any property rights I may have" in biospecimens, or "I voluntarily and freely donate" the biospecimens to a particular institution.

When finalized, the draft document will supersede OHRP's November 15, 1996 guidance entitled, "Exculpatory Language in Informed Consent" and question number 52 in FDA's January 1998 guidance entitled, "Institutional Review Boards Frequently Asked Questions - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators."

The Federal Register notice of availability, the joint draft guidance document, and instructions for how to submit comments can be accessed on the OHRP website at http://www.hhs.gov/ohrp/newsroom/rfc/. The joint draft document can also be accessed on the FDA website at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGudiances/default.htm.