FDA Issues Draft Guidance on Informed Consent Language

September 19, 2011 by Sean Wajert

The FDA has issued draft guidance on the use of "Exculpatory Language in Informed Consent" agreements. The document applies to non-exempt human subject research conducted or supported by the Department of Health and Human Services, and is intended for clinical investigators, institutional review boards, and funding agencies that may be responsible for review or oversight of human subject research conducted or supported by HHS or regulated by FDA.

This document provides guidance on the regulatory prohibition on the inclusion of exculpatory language in informed consent in clinical trials and other research. Readers may know that under federal regulations, no 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 document includes examples of language that OHRP and FDA consider acceptable as well as examples of language that the agencies would consider improperly exculpatory.