

## **Good Clinical Practice Q&A: Focus on Informed Consent**

### **What is exculpatory language and what does it mean?**

Exculpatory language is language or wording that "has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault or guilt." Section 46.116 of 45 CFR and section 50.20 of 21 CFR state that, "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." Thus, it may be permissible to put a waiver in an informed consent document explaining a legal right a subject may have, but under the very limited condition that the waiver does not have the general effect of freeing or appearing to free an individual or an entity from responsibility for malpractice or negligence, or from blame, fault or guilt (i.e., the waiver is not exculpatory).

### **Source**

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at <http://www.barnettinternational.com> in electronic and paper form.