

## Good Clinical Practice Q&A: Focus on ICH IRB Guidelines

### **Does the ICH GCP guideline (E6) feature any IRB-related provisions different from those in the FDA'S existing GCP regulations/standards?**

Yes. In fact, the ICH guideline does not address several of the specific IRB-related requirements contained in FDA regulations. The ICH guideline, however, states that an IRB "should comply with GCP and with the applicable regulatory requirement(s)," a statement that emphasizes the preeminence of FDA requirements in FDA-regulated studies.

Conversely, there are some IRB-related provisions within the ICH guideline that are not addressed in FDA regulations.

While the FDA emphasizes that the ICH GCP guideline is entirely consistent with its own GCP standards, there are several IRB-related provisions that do differ in emphasis or specificity. Since the ICH GCP guideline was released in 1997, several IRB-related differences have been noted, including the following:

- The ICH guideline specifically calls for an IRB review of subject recruitment procedures, the investigator's brochure, payments and compensation to study subjects, and the curriculum vitae of the investigators. FDA regulations require IRBs to review "all research activities," which is generally understood to include all these elements. The FDA also has guidance documents calling for IRB review of certain recruitment materials and practices.
- FDA regulations allow an expedited initial review of certain types of studies that involve no more than minimal risk. The ICH GCP guideline has no such provision.
- The ICH GCP guideline calls on IRBs, when asked, to provide copies of their written procedures and membership lists to investigators, sponsors, or regulatory authorities. FDA regulations require only that IRBs provide such information to regulatory authorities upon request.
- The ICH GCP guideline calls for IRBs to review investigator qualifications. Although the FDA regulations do not specifically require IRB review of the qualifications of the investigator and the study staff, IRBs consider such a review a necessary part of fulfilling the requirements of 21 CFR 56.111 – Criteria for IRB approval of research.
- For subjects who can be enrolled only with the consent of their legally acceptable representative, the ICH GCP guideline calls for the assent of the subjects as well (i.e., if the subject is capable). This includes adults as well as children (4.8.12).
- The ICH GCP guideline recommends that participation in nontherapeutic trials be restricted to those who personally give consent and sign and date the consent form (4.8.13).
- The ICH GCP guideline permits those who cannot personally provide their consent to participate in nontherapeutic trials when all of the following conditions are fulfilled: (a) the objectives of the trial cannot be met by enrolling only subjects who can personally give consent; (b) the foreseeable risks to the subjects are low; (c) the negative impact on the subject's well-being is minimized and low; (d) the trial is not prohibited by law; and (e) the approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/favorable opinion covers this aspect (4.8.14).

- The ICH GCP guideline recommends that the informed consent form be signed and dated by the person conducting the consent interview as well as the subject or legally acceptable representative (4.8.8).
- The ICH GCP guideline specifically recommends that the responsibilities of the study subject be explained in the informed consent form (4.8.10(e)).<sup>1</sup>

### **Reference**

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2005, pg. 137-138

### **Source**

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>